The effectiveness of the Brain Integration Programme

A Dutch community reintegration programme for patients with chronic acquired brain injury

Gerrit Jan Geurtsen

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Promotor	Prof. dr. ACH Geurts
Copromotores	Dr. CM van Heugten, universiteit Maastricht Dr. R Meijer
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Paranimfen	Janny van Ommen Juan Martina

voor wijlen mijn vader, mijn moeder en Jeroen

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1
General introduction

Acquired brain injury is defined as cerebral damage that occurs after birth, unrelated to congenital deficits, developmental disorders, or processes that progressively affect the brain (1). Most frequent aetiologies of acquired brain injury are stroke, traumatic brain injury, brain tumour, encephalitis and hypoxia. Of these aetiologies stroke and traumatic brain injury are the most common. In The Netherlands, the incidence of stroke is approximately 35,500 persons per year and the prevalence is estimated to be 250,000 persons (2). The incidence of traumatic brain injury is estimated to be 35,000 persons per year in the Netherlands, of which approximately 14,000 are admitted to an acute-care hospital (3).

Many individuals with acquired brain injury exhibit a variety of abnormalities, especially in the areas of physical functioning, cognition, emotion and behaviour (1). Despite the fact that most patients receive primary rehabilitation after hospitalization for their injuries and although cognitive, emotional and behavioural problems may reside spontaneously or as a result of rehabilitation (4), at 3–7 years post injury, 45–67% of the patients with traumatic brain injury (5) still suffer from persistent disturbances of cognition, emotion and behaviour. These disturbances can hamper their societal participation and community re-integration (6) and may have a tremendous economic impact as well. The societal and economic consequences of acquired brain injury do not only apply to adults. Children who sustain acquired brain injury at a young age may face similar problems when they grow older. Even more striking, the cognitive, emotional and behavioural problems in children with moderate to severe brain injury may become manifest only at a later stage of their development (7). This phenomenon is due to the increasing complexity of the demands imposed by the environment when children grow older, especially when they are adolescents, a concept that is known as 'growing into deficits' (8).

Given the variety of cognitive, behavioural and emotional disturbances resulting from acquired brain injury (9, 10) and their socio-economic impact, the rehabilitation of *all* psychosocial problems should be a core element in the treatment of patients with moderate to severe brain injury. Remarkably, however, patients with subsequent psychiatric disorders (e.g. substance abuse problems) are often excluded from regular rehabilitation programmes (11). Yet, also patients with severe psychosocial or psychiatric problems after brain injury should receive adequate rehabilitation, even though they may need an adjusted or sheltered living and working environment in the future. These environmental adaptations to facilitate community re-integration aim to establish an appropriate match between individual possibilities and limitations (12, 13, 14). Environmental adaptation also encompasses the selection of an appropriate environment for the patient and his/her caregivers.

Indeed, acquired brain injury not only affects the patients, but also their caregivers. Adequate rehabilitation of these (often relatively young) individuals will reduce secondary societal problems and prevent considerable long term social and economic costs (15). Therefore, rehabilitation of patients with severe psychosocial or psychiatric problems that leads to a better community re-integration will be beneficial to the patients, their caregivers as well as to the society.

During the last decades, several comprehensive programmes have been developed for patients with acquired brain injury all over the world that are directed at the complex psychosocial problems as mentioned above. Malec and Basford (16) classified rehabilitation programmes for the chronic psychosocial sequelae:

1. neurobehavioral programmes;
2. residential community re-integration programmes;
3. comprehensive (holistic) day treatment programmes;
4. outpatient community re-entry programmes; and
5. community-based services (continuation of care).

Whereas the first three types are comprehensive treatment programmes aiming at a wide range of problems, the outpatient community re-entry programme focuses on merely a few circumscribed goals as targets of rehabilitation. This latter programme is meant for patients who function quite independently in daily life, but require psycho-education or the learning of adjusted cognitive strategies to optimize their functioning, well-being and social reintegration (17, 18). The community-based services contain a variety of short- or long-term community support by patient associations and support groups (16). The comprehensive programmes, on the other hand, are much more intensive and meant for patients who experience generalized problems in functioning independently. In addition, these comprehensive programmes explicitly involve the caregivers in the rehabilitation process. Of the comprehensive programmes, neurobehavioral programmes are residential programmes that provide intensive behavioural treatment for patients with severe behavioural disturbances due to their brain injury. Residential community re-integration programmes provide integrated cognitive, emotional, behavioural and vocational rehabilitation for patients with psychosocial problems in one or more of these areas. Among the comprehensive programmes, the day treatment programmes are the only outpatient programmes, offering integrated multimodal rehabilitation directed specifically at improvement of awareness and emotional well-being (16).

The Brain Integration Programme

The Brain Integration Programme (BIP) is the only residential community re-integration programme in The Netherlands. It is offered in the major rehabilitation centre of the Arnhem region (Groot Klimmendaal), which has a tertiary function for residential community re-integration after acquired brain injury. As a consequence, most patients are referred by other rehabilitation centres from all over The Netherlands. The majority of these patients have undergone some form of primary rehabilitation after their brain injury, often several years before admission to the BIP. Thus, the BIP focuses on patients in the chronic phase (at least 6 months) after brain injury.

Malec and Basford (16) have defined residential community reintegration programmes as providing 'integrated cognitive, emotional, behavioural, physical, and vocational rehabilitation to patients who cannot participate in outpatient programs either because of severe cognitive and behavioural impairments or the unavailability of outpatient services.' The Dutch BIP fits exactly into this definition, although it focuses on the chronic stage of brain injury in patients for whom previous rehabilitation attempts failed or remained unsatisfactory. At the start of the development of the BIP, in the years 2000 and 2001, very little was known about the effectiveness of residential community reintegration programmes such as the BIP. Hence, a deliberate choice was made to supplement the clinical endeavour with a series of consecutive studies aiming to underscore its (cost-)effectiveness.

Aims

The general aim of the studies reported in this thesis is to describe and enhance the level of evidence of community re-integration programmes. More specifically, this thesis aims to investigate the effectiveness of the Dutch residential community re-integration programme (The Brain Integration Programme / BIP) for patients with chronic acquired brain injury and persistent psychosocial problems. The research questions were:

1. What is the general effectiveness of comprehensive rehabilitation programmes in patients with acquired brain injury? Do patient characteristics differ between the various types of programmes and what are the essential ingredients of the applied interventions?
2. Is the BIP effective in the domains of emotional well-being, quality of life, level of community integration, employability and living situation? Are the effects maintained after one-year follow up?

3. Can the effects of the BIP be attributed to the treatment itself and what is the possible influence of spontaneous recovery?
4. Can changes in the emotional burden on caregivers of patients with acquired brain injury be assessed?
5. Does offering the BIP to patients with acquired brain injury have a beneficial effect on the caregivers as well?
6. Is the BIP cost effective?

Outline

To answer the above-mentioned research questions, this thesis is outlined as follows: **Chapter 2** focuses on the scientific evidence concerning comprehensive rehabilitation programmes for patients with chronic acquired brain injury. A systematic review is conducted with the aim to determine the 'state of the art' with regard to the effectiveness of community re-integration programmes and other comprehensive rehabilitation programmes to improve psychosocial functioning in brain injured patients (question 1).

Chapter 3 provides a description of the content of the Brain Integration Programme as well as its treatment intensity, duration and staff composition. We present a prospective cohort study with a one year follow up assessing the effectiveness of the Brain Integration Programme on work situation/employability, living situation and emotional well-being in 24 patients (question 2).

Chapter 4 also focuses on the effect of the Brain Integration Programme, but in a study using a waiting list period as a form of within-subjects control. We report the results of a new prospective study with a three-months waiting list period and a one year follow up to further evidence the effectiveness of the Brain Integration Programme on independent living, societal participation, emotional well-being and quality of life in larger sample of patients (n=70) (questions 2 and 3).

Chapter 5 is directed at the assessment of emotional burden in caregivers. Merely a few standardized outcome measures aimed at caregivers of patients with brain injury have been developed. Moreover, information about responsiveness of these existing outcome measures is lacking. In this chapter, the psychometric properties are reported for a new instrument, the Involvement Evaluation Questionnaire for Brain Injury (IEQ-BI). The IEQ-BI was based on the Involvement Evaluation Questionnaire (19), which was developed to assess the emotional burden in caregivers. The IEQ-BI was adapted for the brain injury population and, for the first time, used in caregivers of brain injured patients (question 4).

Chapter 6 reports the effectiveness of the Brain Integration Programme on caregivers' emotional burden and on family functioning. The IEQ-BI as investigated in chapter 5 was used to assess the emotional burden in the caregivers of the patients enrolled in the study of chapter 4. Because it took time to develop and validate this instrument, it was added to the outcome measures only some time after the start of the study of chapter 4. As a result, only 41 caregivers participated in the study reported in this chapter (question 5).

Chapter 7 describes a cost analysis of the Brain Integration Programme. A study was conducted to evaluate the costs associated with healthcare, informal care and productivity before the treatment, the costs of the treatment itself, and the costs related to healthcare, informal care and productivity during follow up. The costs before and after the Brain Integration Programme were compared and this difference was compared to the treatment costs (question 6).

In **Chapter 8** the results presented in this thesis are integrated and discussed.

In **Chapter 9** the results presented in this thesis are summarized.

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2
Comprehensive rehabilitation programmes in the chronic phase after severe brain injury
a systematic review

Gert J Geurtsen
Caroline M van Heugten
Juan D Martina
Alexander CH Geurts

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Abstract

Objective: The aim of this study was to perform a systematic review on the effectiveness of comprehensive rehabilitation programmes for adults in the chronic phase after severe acquired brain injury.

Method: PubMed, PsychINFO and PsychLit were searched for articles published between 1990 and 2008 and a quality assessment was performed. The comprehensive programmes were subdivided into neurobehavioral interventions, residential community reintegration and day-treatment programmes. The extracted data included study characteristics, patient characteristics and intervention characteristics.

Results: Thirteen studies met pre-established criteria. Two studies were randomized controlled trials, 5 were controlled comparative studies and 6 were uncontrolled longitudinal cohort studies. Overall, their methodological quality was limited. The investigated programmes led to substantial improvement in daily life functioning and community integration of severe chronic brain injury patients, with lasting effects at follow-up. Day-treatment programmes had the highest level of evidence.

Conclusions: Comprehensive rehabilitation programmes appear to be effective in terms of a reduction in psychosocial problems, a higher level of community integration and an increase in employment. Although this is the first review to differentiate between specific programmes, clear-cut clinical recommendations cannot possible yet be set out due to limited methodological quality and poor description of patient and intervention characteristics. Specific recommendations for future studies are given.

Keywords: brain injury, rehabilitation, comprehensive rehabilitation, review, adult, middle aged

Introduction

Severe acquired brain injury can have a tremendous impact on patients and family members. They must learn to live with a diminished potential for physical, emotional, cognitive, and social functioning (1). Many patients with severe acquired brain injury receive primary rehabilitation after hospital care. Carney et al. (2) consider 'functioning as independently as possible in the patient's own home and in society' the main goal of rehabilitation. To reach this goal, the rehabilitation process after brain injury needs to attain optimal community reintegration, including a good balance between social and vocational functioning, taking into account individual limitations (3). The ultimate goal is to gain a satisfying quality of life.

Apart from the direct consequences of injury such as cognitive, emotional, behavioural problems and an impaired awareness of limitations (4), some patients develop secondary psychosocial problems later in life. These problems encompass anxiety, depression, and even alcohol and drug dependencies (5). These psychosocial problems in the chronic phase often hinder independent functioning and participation in society. The complexity and magnitude of these problems may require specialized comprehensive rehabilitation. Several comprehensive rehabilitation programmes addressing the long-term psychosocial consequences of brain injury have been developed (6). In their review, Malec & Basford (6) classified the comprehensive rehabilitation programmes for chronic sequelae of brain injury into:

1. Neurobehavioral programmes: being 'residential programmes that provide intensive behavioural treatment to brain injury patients with severe behavioural disturbances;'
2. Residential community reintegration programmes: providing 'integrated cognitive, emotional, behavioural, physical, and vocational rehabilitation to patients who cannot participate in outpatient programmes because of either severe cognitive and behavioural impairments or the unavailability of outpatient services;' and
3. Holistic day-treatment programmes: offering 'integrated, multimodal rehabilitation as defined and described by Ben-Yishay & Prigatano (7).'

Cicerone et al. (8, 9) performed 2 literature reviews on the effects of cognitive and psychosocial rehabilitation, including research published until 2002. They stated that 'there is also evidence that gains in community functioning can be achieved by patients one or more years post injury' and recommended comprehensive rehabilitation as a practice guideline for moderate to severe traumatic brain injury (TBI). However, they did not distinguish between the above-mentioned types of comprehensive treatment programmes, nor did they systematically address the impact of late rehabilitation.

Turner-Stokes (10) recently combined a Cochrane review (previously published in 2005) with an approach using less rigorous design demands, yet excluding low quality studies. She stated that: 'although there is encouraging data from non-randomized clinical trials to support the benefits of behavioural management programmes, community rehabilitation and long-term intervention, this evidence is not yet sufficient to support strong recommendations.' This review contained only 4 studies concerning late rehabilitation and the precise period for the inclusion of studies was not indicated. Moreover, the focus was primarily on the comparison of the 2 review approaches, whereas the specific patient characteristics and the content of the different comprehensive treatment programmes were not discussed.

Hence, little is known about the effectiveness of comprehensive treatment programmes for patients in the chronic phase after severe brain injury in view of their specific goals. Indeed, substantial differences between studies can be expected regarding the applied interventions within the various comprehensive programmes (i.e. neurobehavioural, residential community reintegration and holistic day-treatment), based on different patient characteristics. To our knowledge, no systematic review has yet been conducted to address these specific issues. The aim of this review was, therefore, to systematically address the following questions:

1. Are the different comprehensive treatment programmes for the management of long-term psychosocial problems in patients with severe acquired brain injury effective in terms of reducing these problems and improving community integration?;
2. What are the specific patient characteristics for the various comprehensive treatment programmes?; and
3. What are the essential intervention characteristics of these programmes?

Methods

Selection of articles

A systematic literature search was performed in the primary electronic databases covering this research area: PubMed, PsychINFO, and PsychLit, including articles published between 1990 and 2008. The year 1990 was chosen as a starting point because Turner-Stokes (10) and Cicerone et al. (8, 9) covered the period before 1990 and found no high-quality studies concerning comprehensive rehabilitation programmes for chronic brain injury patients. A quick search done by the authors of this review confirmed this finding. Details of the search strategies are presented in Appendix I. Grey literature was identified by additional hand searching of the reference lists of the review articles on evidence-based cognitive rehabilitation (2, 8-11). Moreover, reference lists from the other identified articles were screened

to complete the initial list of references. The first author performed the literature search as well as the primary selection of articles based on their abstracts. The primary selection of articles for this review was performed based on the criteria as described in Table 1. When selection was not possible based on the abstract alone, or when abstracts were not available, inclusion or exclusion was based on the full text versions.

Table 1. **Inclusion criteria for the selection of publications**

	Inclusion criteria
Participants	Non-progressive severe acquired brain injury (TBI, Stroke, Tumour, hypoxia, encephalitis) in the chronic phase (>1 year)
Treatment programmes	Neurobehavioral programmes, residential community reintegration programmes or (holistic) day-treatment programmes
Type of study	RCT, comparative or uncontrolled longitudinal cohort studies
Publication type	Peer-reviewed journal articles
Year of publication	1990–2008
Language	English
Age	Adults (19-64 years)

RCT = randomized controlled trial; **TBI** = traumatic brain injury.

Studies were included only when they addressed the effect of comprehensive treatment in a randomized controlled trial (RCT), a controlled comparative study or an uncontrolled longitudinal cohort study. Cross-sectional studies or reviews were excluded, because these study designs cannot assess treatment effects or deliver new (original) information on treatment effects, respectively. Furthermore, studies could be included when they addressed the chronic phase of severe acquired brain injury in adult patients, aged 19 to 64 years. For this specific purpose, 'chronic' was operationalized as one year post-onset (6). The majority (>50%) of the patients included in the study had to be in the chronic phase, or the results of the chronic patients had to be described separately.

Quality assessment

After the first selection, the methodological quality of the RCTs was assessed using the CONSORT Statement Checklist (12-16). The quality of potentially relevant articles with other study designs was judged using an adaptation of the Consort Statement, which was constructed in a consensus meeting with all authors. A set of minimal criteria for internal validity was established. Studies were definitively included when they fulfilled each of the following criteria:

1. the inclusion criteria were described;
2. the content of the intervention was described at least globally;

3. the number of patients was a minimum of 20 for uncontrolled cohort studies and at least 10 patients per treatment condition for controlled comparative studies or RCTs;
4. effect sizes and statistical significance were reported;
5. at least one brain injury severity measure was described; and
6. loss to follow-up was less than 20% (17).

Data extraction

When the methodological quality was considered sufficient, the first (GJG) and second (CvH) authors reviewed the articles separately and extracted the following data:
1. study characteristics (design, outcome domains/measures, duration of follow-up, and reported effects;
2. patient characteristics (in- and exclusion criteria, number of participants, sex, age, aetiology, severity, time post onset, baseline functioning); and
3. intervention characteristics (content, duration, intensity, in- or outpatient treatment, rehabilitation team). Consensus was obtained in all instances and no discrepancies had to be settled by an independent third reviewer.

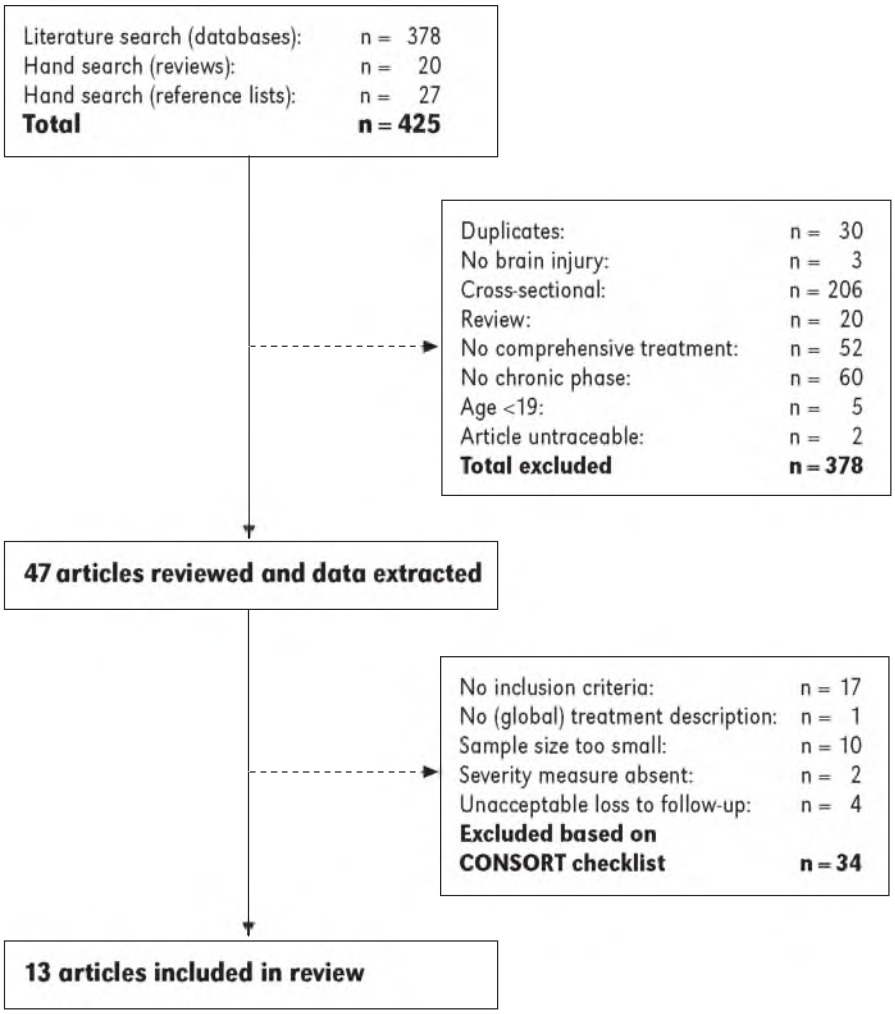
Results

Selection and assessment of studies

The primary literature search of databases, the hand search of the reference lists of review articles (2, 8-11), and the screening of the reference lists from all identified articles resulted in 425 potentially relevant studies. The primary selection based on title, abstract, and (when necessary) full text yielded 47 potentially relevant studies. These 47 studies were subjected to quality assessment, after which 13 studies were finally included for review (Figure 1).

The characteristics of the design, patient population, and the treatment programme of the 13 selected studies are summarized in Tables 2–4, respectively. The studies can be categorized based on the applied treatment programme using the definitions set out by Malec & Basford (6): neurobehavioral programmes (n=1), residential community reintegration programmes (n=3), and day-treatment programmes (n=9).

Figure 1. **Flowchart literature search**



Study outcomes

The applied study designs, measurement instruments and observed treatment effects are described in Table 2. Two studies were RCTs (18, 19) and 5 other studies were (nonrandomised) controlled comparative studies (20-24). Two of these used matching (22, 24). The remaining 6 studies were uncontrolled longitudinal cohort studies. Study outcomes are discussed on the basis of study design and applied treatment programme.

Table 2. **Treatment programmes**

Author, Year (Ref)	Design / Follow up (FU) time	Outcome domains (measures)
Neurobehavioral treatment programmes		
Wood et al. 1999 (30)	Uncontrolled retrospective study Selection: minimum treatment time 6 months pre + post + FU (minimum 12 months): FU mean 33 months (range 12-61)	Living arrangement Employment Care support Neurobehavioral problems Cost of care
Residential community reintegration treatment programmes		
Willer et al. 1999 (24)	Controlled study using individual systematic matching procedure Admission, discharge, 1 year FU. Control FU for 20 of 23 patients	HALS CIQ
Gray & Burnham, 2000 (28)	Uncontrolled cohort study: Admission, discharge. No FU	Level of care required at discharge for 305 of 349 patients (87.7%) RDRS for 305 of 349 patients (87.4%) FIM+FAM for 197 of 349 patients (56.4%)
Geurtsen et al. 2008 (29)	Cohort study: Admission, discharge, FU 1 year.	CIQ CES-D EuroQol ERS Living arrangement Work
Day-treatment programmes		
Ruff & Nieman, 1990 (19)	RCT with 2 pre-treatment measurements and 1 post-treatment measurement. No FU	KAS social obstreperousness KAS psychoticism KAS withdrawn/depression
Christensen 1992 (25)	Uncontrolled cohort study; Pre-injury, pre-treatment, post-treatment, FU approxiamtely 1 year.	Work only Work (education + work-trial + gainful employment).
Rattok et al. 1992 (20)	Controlled trial with three treatment packages administered consecutively in same facility with same staff. Pre-treatment, post-treatment measurements. Randomisation not specified, no blinding. No FU, only vocational outcome at 3 and 9 months	Neuropsychological measures Functional behavioural measures: competence in daily live Intra- and interpersonal functioning Vocational outcome at 3 and 9 months
Teasdale et al. 1993 (26)	Uncontrolled cohort study; Pre-injury, pre-treatment, post-treatment, FU approxiamtely 1 year. Comparison of TBI and stroke patients.	Marital status Help in living situation Utilization of health services Work % working/education Work hours per week Leisure activities hours per week
Malec 2001 (27)	Uncontrolled cohort study: Pre, post, FU 1 year.	Work (VIS) unemployed Independent living (ILS) reaching individual goals (GAS) level of disability (PAI / MPAI)

Raw scores, % of change, significance	Reported effect*
Home/supported housing n=33 rose to n=51 post and n=54 at FU, p=0.0001	+ compared to themselves
Pre employment/education 4%, post ?, FU 60.5%, p=0.0001	+ compared to themselves
Subdivided per time-since-injury p=0.0001	+ compared to themselves
No total pre-post-fu raw data reported. Subdivided per time-since-injury	+ compared to themselves
No total pre-post-fu raw data reported. Subdivided per time-since-injury	+ compared to themselves
E Total pre 20.39, post 14.62, FU 15.62	+
C Total pre 20.30, post 18.98, FU 19.20	
p<0.001 form pre-post, p>0.05 post-FU	
Total CIQ group by trial interaction p<0.001	+/-
85.6% discharged to community locations; pre-post p<0.001	+
Only significance reported: TBI pre-post p<0.001	+
Motor pre-post p<0.001	+
Cognitive pre-post p<0.001	+
Pre 14.0, post 17.2, FU 16.8: pre-post p<0.05, FU p>0.05	+, maintained at FU
Pre 20.1, post 12.7, FU 15.4: pre-post p<0.05, FU p>0.05	+, maintained at FU
Pre 9.5, post 8.3, FU 8.4: pre-post p<0.05, FU p>0.05	+, maintained at FU
Pre 2.3, post 3.2, FU 4.3: pre-post p>0.05, FU p<0.05	o post, + at FU
Independent living pre 41.6% rose to 75% post and 71% at FU	+, maintained at FU
Work pre 37.5% rose to 46% post and 58% at FU	+, further increase at FU
E pre 58.8 post 62.8; C pre 67.9 post 63.2; p>0.10	o
E pre 15.8 post 16.0; C pre 18.3 post 20.3; p>0.10	o
E pre 17.9 post 17.7; C pre 19.4 post 18.7; p>0.10	o
No raw data presented, % not in table, only in figure Pre-post p<0.001; post-FU p>0.1 Pre-post p<0.001; post-FU p>0.1	+ pre-post treatment, o at FU.
41 raw scores presented pre and post divided in near transfer (trained tasks) and far transfer (untrained tasks). Near: p varying from 0.001 to not significant in treatment x outcome ANOVA. Far: all not significant.	+ pre-post treatment, not much difference in treatment mix.
No raw data presented, only number of patients achieving significant improvement. E1-E3 p<0.01, E1-E2 p not significant.	+ pre-post treatment: E1 > E3, E2 seems > E3.
4 raw scores presented pre and post; treatment x outcome ANOVA. All of them not significant.	+ pre-post treatment, not much difference in treatment mix.
Open environment: E1 70%, 52%; E2 78%, 78%; E3 83%, 61%. No p presented, no significant differences between treatments.	+ pre-post treatment, no difference in treatment mix.
Pre-injury 42%, pre 28% post 28%, FU 40% p=0.06	o pre-post treatment, o at FU
Pre-injury 3%, pre 31% post 14%, FU 9% pre-post p<0.05	+ pre-post treatment, o at FU
Pre 2.4 post 0.7, FU 0.8, pre-post p<0.05	+ pre-post treatment, o at FU
Pre-injury 95%, pre 22% post 39%, FU 40% pre-post p<0.05	+ pre-post treatment, o at FU
Pre-injury 37.9, pre 9.2, post 15.8, FU 19.9 pre-post p<0.05	+ pre-post treatment, o at FU
Pre-injury 8.6, pre 5.4, post 5.1, FU 9.4 pre-post p>0.05, pre-FU p<0.05	o pre-post treatment, + at FU
Pre 84%, post 26%, FU 27% No p presented	+ compared to themselves.
Pre 47%, post 69%, FU 72% No p presented	+ compared to themselves.
Post 81% No p presented	+ compared to themselves.
Pre 546.3, post 448.3; pre-post p<0.0001	+ compared to themselves.

Table 2. **Treatment programmes** (continued)

Author, Year (Ref)	**Design / Follow up (FU) time**	**Outcome domains (measures)**
Cicerone et al. 2004 (21)	Uncontrolled comparative study; no randomization but allocation to treatment (with systematic bias in allocation): Pre, post. No FU.	Community Integration (CIQ) Satisfaction with community integration (QCIQ) Satisfaction with neuropsychologic functioning (QCIQ)
Sarajuuri et al. 2005 (22)	Matched comparative study; no randomization but matching: Pre, FU 2 years.	Productivity (working, studying, volunteer work)
Hashimoto et al. 2006 (23)	Comparative study; no randomization E + C. Pre + post. E treatment, C convenience sample No FU Note: Selection or matching not specified.	ADL (FIM/FAM) Societal participation (CIQ)
Cicerone et al. 2008 (18)	RCT with pre-treatment, post-treatment and FU 6 months.	Community Integration (CIQ) Perceived Quality of Life (PQOL) Neuropsychologic functioning Perceived self-efficacy Vocational activity (VIS)

* Results are summarized as reported in the original studies

+ = a positive difference in favour of the eperimental group/compared to themselves;
o = no difference between the group/compared to themselves;
– = a negative difference in adverse of the experimental group/compared to themselves;

C = control; **CDT** = Comprehensive Day-treatment; **CES-D** = Centre for Epidemiological Studies-Depression; **CIQ** = Community Integration Questionnaire; **E** = experimental; **ERS** = Employability Rating Scale; **ES** = effect size; **EuroQol** = EuroQol group quality of life scale; **FAM** = Functional Assessment Measure; **FIM** = Functional Independence Measure; **FU** = Follow-up; **GAS** = Goal Attainment Scaling; **HALS** = Modified Health and Activity Limitation Survey; **ICRP** = Intensive Cognitive Rehabilitation Programme; **ILS** = Independent Living Scale; **KAS** = Katz Adjustment Scale; **MPAI** = Mayo-Portland Adaptability Inventory; **PAI** = Portland Adaptability Inventory; **PQoL** = Perceived Quality of Life; **QCIQ** = Quality of Community Integration Questionnaire; **RCT** = randomized controlled trial; **RDRS** = Rappaport Disability Rating Scale; **SRP** = Standard Neurorehabilitation; **VIS** = Vocational Independence Scale.

Randomized controlled trials

Day-treatment programmes. In a RCT by Cicerone et al. (18) the experimental treatment was a comprehensive day-treatment group programme, emphasizing the integration of interventions directed at deficits, emotional difficulties and interpersonal behaviour with feedback from the group on the performance of the patient and active self-evaluation aimed at adaptation to chronic limitations. The control

Raw scores, % of change, significance	Reported effect*
ICRP Total pre 11.6, post 16.8 SRP Total pre 13.7, post 16.1 ANOVA p=0.021	+ ICRP > SRP
ICRP post 27.1, SRP post 29.7 p<0.01	– SRP > ICRP
ICRP post 16.7, SRP post 18.2 p>0.05	o
E 17 89%, C 11 55% p=0.017	+ E > C
17 FIM/FAM change scores in article comparison between both groups	+ on speech, problem solving, memory, attention, social integration (p<0.05) o on rest (p>0.05)
Total change E 3.52, C 0.58 p<0.05	+ on social, productivity and total score. o on home score
ICRP Total pre 11.2, post 12.9, FU 13.2 SRP Total pre 12.1, post 11.7, FU 12.9 ES=0.59	+ ICRP > SRP
ICRP pre 59.0, post 66.8, FU 66.1 SRP pre 61.2, post 62.2, FU 59.6 ES=0.30	+ ICRP > SRP
ICRP T-score pre 36.6, post 39.5 SRP T-score pre 35.9, post 39.5 ES=–0.20-0.09	o SRP = ICRP
ICRP Total pre 84.3, post 94.1, FU 92.4 SRP Total pre 82.6, post 84.8, FU 81.9 ES=0.26	+ ICRP > SRP
ICRP pre 3, post 16, FU 20 SRP pre 4, post 7, FU 14	+ ICRP > SRP

treatment was an interdisciplinary individual day-treatment programme targeting deficits including the retraining of cognitive functions. Both the experimental and control group comprised 34 patients. Treatment duration was 15 h per week for 16 weeks. Validated instruments (Community Integration Questionnaire (CIQ)) and the Perceived Quality of Life scale (PQoL)) were used as primary outcome measures and the follow-up period was 6 months. The experimental treatment had a moderate clinical effect on community functioning (assessed with CIQ) and a small clinical effect on life satisfaction (assessed with the PQoL) compared to the control treatment. The experimental treatment showed significantly greater improvements than the control treatment and these gains were maintained at 6 months follow-up.

The RCT performed by Ruff and Nieman (19) also compared two day-treatment programmes. The experimental group received cognitive remediation and problem-solving training, whereas the control group received a programme aimed at enhancing psychosocial functioning and activities of daily living. Both the experimental and control groups comprised 12 patients who received treatment for 12 h per week during 8 weeks. A validated outcome instrument (Katz Adjustment Scale

(KAS)) was used, but there was no follow-up. Both treatments appeared equally effective: patients became less socially withdrawn and depressed. Unfortunately, despite randomization, there were baseline differences for coma duration with a shorter duration in the experimental group. This inequality at baseline was most likely due to the small number of patients. Another drawback of this study was the potential lack of contrast between the experimental and control treatment.

Residential community reintegration programmes. No RCT was identified.

Neurobehavioral programmes. No RCT was identified.

Controlled comparative studies

Day-treatment programmes. In the first comparative study, Rattock et al. (20) compared 3 day-treatment mixes. Their treatment programme was changed over the years and patients undergoing these separate mixes were compared. Differences in treatment were related to the availability and duration of cognitive remediation, the participation in small-group interpersonal exercises and the duration of personal counselling. The treatment groups comprised 18–23 patients. Patients received 400 h of treatment during 20 consecutive weeks. A combination of validated neuropsychological measures (such as the Wechsler Adult Intelligence Scale, Benton Visual Retention Test, etc.) and descriptive non-validated instruments was used. There was a follow-up only with regard to employability at 3 and 9 months. The description of absolute effect sizes was limited. All treatment mixes appeared effective on most neuropsychological measures, behavioural measures, and measures of productivity. However, there were only minor differences in efficacy between the treatment mixes.

In the second comparative study, Cicerone et al. (21) compared 56 TBI patients who were allocated either to an experimental integrated comprehensive treatment or to a control treatment which was less intensive and less structured. There was a pre- and post- treatment measurement with a validated instrument (CIQ), but no follow-up. The experimental treatment seemed to result in a higher level of community integration, but allocation bias was a major confounding factor (21).

In the third comparative study, Sarajuuri et al. (22) offered day-treatment to 19 patients who were compared to patients with similar demographic and injury characteristics and who were seen for neuropsychological assessment only. The treatment duration was 7.5 h per day, 5 days per week for 6 weeks. After the training, the patients received neuropsychological support and coaching in work or education. There was no direct post-treatment measurement, only a follow-up measurement at 2 years. This study showed significant improvements in terms of

productivity compared with the control group. Only descriptive instruments of work and education were used as outcome measures.

Hashimoto et al. (23) compared the effects of day-treatment with a control intervention in 25 and 12 patients, respectively. All patients were included from the same hospital and at the same time, but the selection procedure was not described. The treatment duration varied per group from 4 to 16 hours per week, for 3-6 months. The mean duration of treatment was 100 h. There were pre- and post-treatment measurements, but no follow-up. Furthermore, the control treatment was not specified. Despite this, the authors reported positive effects on the validated outcome measures (CIQ, Functional Indepence Measure + Functional Assessment Measure (FIM/FAM)) in the intervention group compared with the control group.

Residential community reintegration programmes. As for residential treatment, in the fifth comparative study by Willer et al. (24), 23 patients were compared with a matched sample of 23 patients receiving limited home-based services or outpatient treatment. The residential treatment offered a structured social environment based on neurobehavioral principles in which goal-directed interventions were offered, however, its content was not specified. The duration of the residential treatment was 8 months, but the intensity was not specified. The control group received a variety of home-based or outpatient services of variable intensity and duration. Validated outcome measures were the Modified Health and Activity Limitation Survey (HALS) and the CIQ. The study showed greater improvement in functional abilities and community integration in the group receiving the residential treatment. At one-year follow-up, the functional gains and the level of community integration were maintained.

Neurobehavioral programmes. No comparative study was identified

Uncontrolled longitudinal cohort studies

Day-treatment programmes. Two original cohort studies have been conducted on the effects of day-treatment programmes (25, 27). Christensen (25) followed 46 patients and showed a significant increase in working hours after treatment, which was maintained at one-year follow-up. However, only descriptive non-validated instruments were used. Teasdale et al. (26) seemed to present the 36 TBI and stroke patients of the Christensen (25) study with the same results.

Malec (27) followed 96 patients with validated (Portland Adaptability Inventory, Mayo-Portland Adaptability Inventory) and descriptive outcome measures. This study showed positive effects after treatment on employment, diminished care

utilization, and independent living. These effects were maintained at one-year follow-up.

Residential community reintegration programmes. Two cohort studies were published that focused on the effectiveness of residential treatment (28, 29) in addition to the comparative study by Willer et al. (24). Gray and Burnham (28) conducted a historic cohort study using a database of 349 low-functioning patients who did not classify for regular rehabilitation. They used validated instruments (FIM/FAM, Rappaport Disability Rating Scale (RDRS)) and demographic data. They showed significant functional improvements of patients compared with other types of brain injury rehabilitation programmes.

Geurtsen et al. (29) performed a prospective cohort study of 24 patients with behavioural deficits leading to social, emotional, and vocational integration problems. They had a follow-up of one year and used a combination of validated (CIQ, Centre for Epidemiological Studies-Depression, EuroQol group quality of life scale) and descriptive outcome measures. This study showed significant improvements in various domains of community integration (living situation, work) at discharge and at one-year follow-up.

Neurobehavioral programmes. One cohort study was directed at the effects of a neurobehavioral treatment programme (30). The neurobehavioral intervention aimed to restore behavioural and functional skills for semi-independent living in the

Table 3. **Patient characteristics**

Author, Year (Ref)	**Inclusion and exclusion criteria**	**Patients: n, M/F, age**
Neurobehavioural treatment programmes		
Wood et al. 1999 (30)	Unable to live independently and persisting history of aggressive behaviour. Criteria not specified. Minimum of 6 months of rehabilitation.	n=76, Drop-out 0 (0%) M/F: 57/19, Age: M: 38.0 / F: 36.7
Residential community reintegration treatment programmes		
Willer et al. 1999 (24)	E: Severe brain injury, multiple disabilities and behavioural disabilities, often excluded from post-acute rehabilitation and referred to chronic care hospitals. C: from the roster of a support group.	n=52 Drop-out 3 before treatment, 3 at FU: Total 6 (11.5%). M/F: E 20/3, C 20/3 Age: E 33.42 SD 11.31, C 34.78 SD 10.72

community. Descriptive measures for living arrangement, employment, and care utilization were used. The study had a variable follow-up period with a minimum of one year and a mean of 2.8 years, and showed a significant treatment effect in terms of improved living arrangement, hours of care required, and employment. These effects were maintained at follow-up (30).

Patient characteristics

The characteristics of the study populations are described in detail in Table 3. The inclusion criteria were sufficiently described in 6 studies (18, 20, 25, 26, 27, 29). In the other 7 studies the inclusion criteria were described only globally (19, 21-24, 28, 30). Determining what treatment was directed at which type of patient was impossible due to the limited information provided about baseline cognitive or behavioural functioning. Only 2 studies gave a more extended description of functioning and problems before treatment (29, 30). All studies together included 982 patients of which 72.5 % had sustained a TBI. Other diagnoses were stroke/subarachnoid haemorrhage (15.3%), anoxia (3.6%), other brain injuries (5.4%), and non-specified brain injuries (2.9%). The comprehensive treatment programmes were directed at severe and complex brain injury patients (Glasgow Coma Score 3-8, coma duration >6 h or Post Traumatic Amnesia duration >24 h; (31)). The exact numbers of mild, moderate or severe TBI patients were specified in a limited number of studies only (18, 21, 23, 27). The mean age of the patient groups varied from 26.6 to 39.4 years. Overall, 72.3% of the included patients were male, 26.5% were female, whereas 1.2% of the cases remained unspecified in terms of gender.

Aetiology, Time post-onset	**Severity TBI: GCS, Coma duration, PTA duration**	**Baseline functioning (at start treatment)**
TBI 58, Stroke 12, Anoxia 1, encephalitis 1, rest 4. Time post-onset 72.83 months (range 3-332)	PTA 23.5 days	Incapable of independent life in the community, dependent on others for their day to day social and domestic functioning. Neurobehavioural deficits on admission: aggression, disinhibition, mood disorders, impulsiveness, poor insight. Cognitive: not described
TBI Time post-onset 3.05 years	Coma > 72 hours, most (18 of 23) >3 weeks	E: Prior in acute care (1/23), inpatient rehabilitation (7/23), chronic care/psychiatric (7/23), own home/family (8/23), severe behavioural disabilities (not specified), not accepted by other regional programmes, HALS Total 20.39, CIQ Total 10.94. C: lived with family (20/23), inpatient rehabilitation (2/23) or chronic care facility (1/23). HALS Total 20.30, CIQ Total 13.13.

Table 3. **Patient characteristics** (continued)

Author, Year (Ref)	Inclusion and exclusion criteria	Patients: n, M/F, age
Gray & Burnham, 2000 (28)	Severe brain injury, adult age, 'slow to recover' with perceived potential to participate and benefit, but not appropriate for other community- or facility-based rehabilitation programmes.	n=349 Drop-out 0 (0%) M/F: 73.5% / 26.6% Age: 39.4
Geurtsen et al. 2008 (29)	Brain Injury and having severe problems in social areas, emotional areas, and labour/work integration. Exclusion criteria: Suitability for other (outpatient) cognitive rehabilitation programmes, severe disruptive behaviour, complete lack of problem awareness, severe memory problems, and severe drug addiction.	n=24 Drop-out 2 (8.3%) M/F: 75% / 25% Age: 28.5
Day-treatment programmes		
Ruff & Nieman, 1990 (19)	Age between 16-65, moderate to severe head injury (coma at least 1 hour), chronicity between 1-7 years, no premorbid history of psychiatric disorders requiring hospitalization, sufficient cognitive functioning, sufficient expressive and recessive language skills, sufficient vision, at least one functional hand, motivation and availability to participate in 8-week programme and evaluations.	n=24 Drop-out 1 (4.2 %, missing data) E: n=12, M/F 9/3, Age 28.3 (range 18-48) C: n=12, M/F 8/4, Age: 31.1 (range 18-47)
Christensen 1992 (25)	Brain injury, 16 year and older, good family and/or social support, return to employment or education should be feasible, 7 years of grade school, insight into own situation and/or motivation, partly preserved ability to communicate, ambulatory. Exclusion: progressive central nervous system illness, significant history of substance abuse, psychiatric illness requiring treatment, chronic deteriorating illness.	n=46 Drop-out 0 (0 %) M/F 28/18 Age: 30 SD 10.8 (range 16-58)
Rattok et al. 1992 (20)	TBI with at least 1 hour coma or hypoxia with at least 12 hours of coma, at least 1 year post-injury, unsuccessful prior vocational or educational rehabilitation, residence in greater New York metropolitan area during study, age between 18 and 55 years, functional English, at least partial independence in basic self-care, independence in ambulation, at least one functional hand, continence, minimal IQ of 80, motivation for rehabilitation, intact basic level of social appropriateness, manageable in noncoercive environment. No past or present significant psychiatric complications, no history of significant alcohol or drug abuse, no history of sociopathy, no major aphasic or dysarthric difficulties	n=59 Drop-out 0 (0%) E1: n=23, M/F 15/8, Age: median 26.8 E2: n=18, M/F 16/2, Age: median 27.1 E3: n=18, M/F 11/7, Age: median 28.5

Aetiology, Time post-onset	Severity TBI: GCS, Coma duration, PTA duration	Baseline functioning (at start treatment)
TBI 59%, Stroke 16%, SAH 9%, Anoxia 7%, rest 9%, missing 1% Mean 401.1 days	GCS 5.9 PTA in 89.6% > 7 days	RDRS 9.9, FIM+FAM motor score 67.5, FIM+FAM cognitive score 48.4. No description of behavioural or cognitive functioning. Almost 60% were referred form acute care facilities.
TBI 18, Stroke 3, tumour 2, encephalitis 1 Time post-onset: 5.4 years	GCS 5.9 Coma duration 15.1 days (range 3-42 days)	Behaviour: 33% had alcohol and drug abuse problems. 41.6% was living independently, 21% were following education and 37.5% were working. CIQ Total 14.0, CES-D 20.1, ERS 2.3. Cognitive: Many slow in processing information, some had attention deficits, some participants had executive problems. Severe memory problems were infrequent.
Acquired brain injury: aetiology not specified. Time post-onset: E 44.3 months (10-86) C 52.2 months (24-85) Not significantly different.	E coma 25.5 days (range 0.5-47) C coma 48.3 days (range 5-95) Significantly different.	Behaviour and cognitive not described.
TBI 47.8 %, CVA 30.4%, Hypoxia 15.2%, Rest 6.5%. Time post-onset 2.9 years (range 0.5-14.2) NOTE 1: Same patients as in Christensen, Pinner et al 1992. NOTE 2: TBI and CVA seem to be reported in Teasdale (1993) too.	TBI: no coma 4.6%, coma <1 day 18.2%, rest >1 day	Hemi paresis 28%, impairments of fine motor dexterity 24%, dysarthria 13%, ataxia 9%.
Acquired brain injury: 56 TBI and 3 Hypoxia Time post-onset: E1: median 32 months E2: median 33.8 months E3: median 40.2 months	Coma: E1: median 34.3 days E2: median 38.9 days E3: median 36.9 days	E1 BCI 6.2, self-esteem 11.48, self-appraisal 6.35, interpersonal empathy 18.39, social cooperation 19.05 E2 BCI 6.7, self-esteem 13.28, self-appraisal 6.78, interpersonal empathy 19.72, social cooperation 19.17 E3 BCI 7.2, self-esteem 13.12, self-appraisal 6.47, interpersonal empathy 20.82, social cooperation 20.50 41 cognitive tests pre and post measurement. All scores displayed but no description of meaning/ explanation.

Table 3. **Patient characteristics** (continued)

Author, Year (Ref)	Inclusion and exclusion criteria	Patients: n, M/F, age
Teasdale et al. 1993 (26)	Brain Injury, age at least 16, good family and/or social support, subsequent education or employment considered realistic, at least 7 years grade school, insight into own situation, at least partial ability to communicate, ambulatory. No progressive central nervous system illness, no significant history of substance abuse, no long-term psychiatric illness requiring treatment, no chronic deteriorating illness.	n=36 Drop-out 1 (2.8%) TBI: M/F: 73%/27%, Age: 27.2 (SD 9.1). CVA M/F: 43%/57%, Age: 36.4 (SD 12.1)
Malec 2001 (27)	Brain injury, limited self-awareness, cognitive impairments, ineffectual communication and social skills, limited emotional and behavioural self-control. Independent in mobility, functional communication, sufficient memory for carry over of new information, no significant risk to selves or others. Note: only 25% referred for treatment admitted.	n=113 Dropout during treatment 17, loss to FU 1. Total 18 (16%) Remaining N=96 M/F: 73%/27% Age: 34.2
Cicerone et al. 2004 (21)	ICRP: medical stable, independent self-care skills, cognitive able to participate in treatment, TBI, 18 years or older, adequate language expression and comprehension, family member or other participate in treatment plan. Exclusion: current substance abuse or psychiatric disturbance. SRP inclusion and exclusion criteria not specified.	n=56 Drop-out 0 (0%) ICRP n=27, SRP n=29. M/F: ICRP 17/10, SRP 23/6 Age: ICRP 37.8, SRP 37.1
Sarajuuri et al. 2005 (22)	E + C: Inclusion: independence daily life, only slight physical disabilities, age 16-55, completed compulsory education, adequate potential to achieve productivity. Exclusion: significant psychiatric history, alcohol or drug abuse, previous brain injury, another malignant disease during follow up. Matching on: age, sex, education level, injury severity, time since injury, pre-injury employment.	n= 42, drop-out 3 (7.1%). Remaining n=39 described E: n=19, M/F 16/3, Age at injury: 30.5, All TBI, 42.4 months C: n= 20, M/F 17/3, Age at injury: 29.5
Hashimoto et al. 2006 (23)	E + C Near independent in ADL, goal of returning to work or school, having no place to visit frequently except outpatient clinic.	n=37 Drop-out 0 (0%) E: n=25, M/F: 18/7, Age: 26.6 (range 19-56) C: n=12, M/F not specified, Age: 28.7
Cicerone et al. 2008 (18)	Inclusion for rehabilitation: medical stable, independent self-care, clinical judgement to benefit from comprehensive rehabilitation. Inclusion for treatment study: TBI, at least 3 months post-injury, 18-62 years, adequate language expression and comprehension, require at least 4 months comprehensive treatment, clinical appropriate for both treatments, capable of attending treatment 3 days a week, be capable of giving informed consent. Exclusion: active psychiatric illness, substance abuse or pain preventing compliance to treatment.	n=68 Drop-out 6 (8.8 %) ICRP n=34 SRP n=34. M/F: ICRP 25/9 SRP 21/13 Age: ICRP 38.7, SRP 34.5

Aetiology, Time post-onset	Severity TBI: GCS, Coma duration, PTA duration	Baseline functioning (at start treatment)
TBI N=22 CVA N=14 NOTE: Same patients seem to be reported in Christensen et al, 1992. Time post-onset: TBI: 3.1 years (SD 2.8) CVA: 2.6 years (SD 2.2)	TBI: no coma 4.5%, coma <7 days 36.4%, rest >7 days 59.1%	None were active in employment and more than one third had experienced failed attempts to return to work. 31% receiving help pre-treatment. Further characteristics not specified.
TBI 72%, CVA 19%, Rest 9% Time post-onset 4.6 years NOTE: probably partly same patients as Malec 1993. Malec 1993: dec 1986-aug 1991; Malec 2001: 1988-1998.	GCS: Mild TBI 7% Moderate 7% Severe 82%	47% living independently, 84% unemployed, 6% sheltered work, 3% supported, 3% transitional and 4% independent work placement. MPAI-22 score: 546.3, determined mean 102.4 days before treatment. Behaviour and cognitive not described.
All TBI Time post-onset: ICRP 33.9 months, SRP 4.8 months	Moderate to severe TBI 89% Mild TBI 11%	ICRP: CIQ: Total 11.6, Home 3.1, Social 7.0, Productivity 1.4 Neuropsychologic functioning: overall T score: 35.5. Behaviour not described. SRP: CIQ: Total 16.7, Home 3.5, Social 6.8, Productivity 3.4. Behaviour and cognitive not described.
All TBI Time post-onset: 46.6 months	E GCS 7.9 C GCS 8.0	Both groups behaviour and cognitive not described. E 6 (32%) failed in attempting to return to work/school. 1 productive part-time, 18 not productive. C 6 (30%) failed in attempting to return to work/school.
E TBI 22, CVA 2, Tumour 1 Time post-onset 527.3 days C 10 of 12 severe TBI, rest? Time post-onset 487.6 days	E 19 of 25 severe 5 moderate; 1 not clear C 10 of 12 severe	3 used wheelchair and needed some help in ADL, FIM motor range 64-91, FIM Cognition range 17-34, FIM Total range 88-125. WAIS-R VIQ range 63-116, PIQ range 46-125. TIQ range 61-123. CIQ scores not mentioned. Behaviour and cognitive not described.
All TBI Time post-onset 43.3 months.	Severe TBI 59% Moderate TBI 24% Mild TBI 13% Undetermined 3%	4% a previous TBI 13% history of psychiatric illness 21% history of substance abuse ICRP: CIQ: Total 11.2, Home 3.8, Social 6.4, Productivity 1.0 Neuropsychologic functioning: overall T score: 36.6. Behaviour not described. SRP: CIQ: Total 12.1, Home 4.0, Social 7.3, Productivity 0.9. Neuropsychologic functioning: overall T score: 35.9. Behaviour not described.

ADL = Activities Daily Living; **BCI** = Behavioral Competence Index; **BI** = Brain Injury; **C** = control; **CIQ** = Community Integration Questionnaire; **CVA** = Cerebral Vascular Accident; **CES-D** = Centre for Epidemiological Studies-Depression; **E** = experimental; **ERS** = Employability Rating Scale; **FAM** = Functional Assessment Measure; **FIM** = Functional Independence Measure; **FU** = Follow-up; **GCS** = Glasgow Coma Scale; **HALS** = Modified Health and Activity Limitation Survey; **IQ** = Intelligence Quotient; **ICRP** = Intensive Cognitive Rehabilitation Programme; **MPAI** = Mayo-Portland Adaptability Inventory; **PIQ** = Performal IQ; **PTA** = Post Traumatic Amnesia; **SAH** = Subarachnoid Haemorrhage; **SD** = standard deviation; **SRP** = Standard Neurorehabilitation; **TBI** = Traumatic Brain Injury; **TIQ** = Total IQ, **VIQ** = Verbal IQ; **WAIS-R** = Wechsler Adult Intelligence Scale-Revised.

Intervention characteristics

The characteristics of the interventions are described in detail in Table 4. In 6 studies the content of the intervention was described only globally (19, 23, 24, 26, 28, 30). The neurobehavioral intervention (30) was directed at restoring behavioural and functional skills for (semi-)independent living in the community for severely behaviourally disturbed patients. The residential community reintegration programmes had all been developed for specific purposes. One programme was directed at patients who were excluded from regular rehabilitation in the chronic phase (24). Another programme was aimed at low-functioning patients (28) and a third programme was directed at the reintegration of chronic patients with social, emotional and vocational integration problems due to behavioural disorders and/or substance abuse (29). Finally, the applied day-treatment programmes were group programmes directed at cognitive training, and improving self-awareness, coping and compensation skills using neuropsychotherapy (18-23, 25, 26, 27).

Table 4. **Intervention characteristics**

Author, Year (Ref)	Intervention
Neurobehavioural treatment programmes	
Wood et al. 1999 (30)	Social and neurobehavioral rehabilitation directed at recovering behavioural and functional skills for semi-independent living in the community relying heavy on therapy care assistants
Residential community reintegration treatment programmes	
Willer et al. 1999 (24)	E: structured social environment based on neurobehavioral model by trained and guided paraprofessionals; goal-directed rehabilitation: content not specified. C: home-based services provided by licensed professionals (in home or long-term care facility): content not specified.
Gray & Burnham, 2000 (28)	Comprehensive multidisciplinary rehabilitation in a hospital setting for slow-to-recover brain injury patients.

The duration of the applied treatments was often not exactly specified. The neurobehavioral programme lasted 14.3 months (30). The duration of the residential community reintegration programmes was from 28.4 weeks (29) to 51.3 weeks (28). The duration of the day-treatment programmes was the shortest and varied between six weeks (22) and 27.1 weeks (27). The treatment intensity was specified only in four studies (18, 19, 20, 29). One comparative study specified the treatment intensity only for the experimental group (21). The hours of therapy varied from 36 to 400 in day-treatment (18-21) and 254 (29) in a residential treatment programme, whereas the other studies did not report on intensity.

The members of the rehabilitation team were described in only 10 studies (18, 20-24, 25, 27, 28, 29). The neurobehavioral intervention (30) relied on therapy care assistants. It was not specified who coached and trained these assistants. The residential community reintegration programmes were all multidisciplinary (24, 28, 29). The day-treatment programmes varied from therapy by psychologists alone (20) to multidisciplinary interventions (18, 22, 23, 25, 27). Cicerone et al. (18, 21) specified the therapists only for the control treatment. Some studies (19, 26) did not specify the therapists at all. The neurobehavioral programme and residential community reintegration programmes were all inpatient programmes, but Willer et al. (24) used an outpatient group as a control. The day-treatment programmes were given on an outpatient basis, but the patients in the study by Sarajuuri et al. (22) stayed in an inpatient setting during the treatment. Only the day-treatment interventions were described (22).

Treatment characteristics: duration/intensity	**Treatment team**	**In- or out-patient**
Duration mean 14.3 months (range 6-32) Intensity not specified	Relying heavily on therapy care assistants, rather than on professional therapy staff. Staff-patient ratio and treatment team not specified.	Inpatient
E treatment by professionals (physician, OT, PT, ST) and trained paraprofessionals. Duration: E 8 months. C variable range of home-based or outpatient services (support group, OT, PT, neuropsychological). Intensity variable. Duration: C continuously even after 2-3 years Intensity not specified	E: Staff-patient ratio not specified. Treatment team: professionals (physician, OT, PT, ST), neuropsychologist team coordinator and trained paraprofessionals. C: none or OT, PT, neuropsychologist, case manager or home-maker service. Staff-patient ratio not specified.	E: Inpatient C: Outpatient
Duration: mean 359 days Intensity not specified.	Staff-patient ratio not specified. Treatment team: medicine, psychiatry, nursing, PT, OT, dietetics, ST, psychology, neuropsychology, social work, recreation therapy.	Inpatient

Table 4. **Intervention characteristics** (continued)

Author, Year (Ref)	Intervention
Geurtsen et al. 2008 (29)	Three modules (indepentent living, social-emotional, work). Training in safe therapeutic environment with continuous feedback on behaviour. Training skills. Increasingly applying learned skills in daily life at home. Relatives are actively involved and supported.
Day-treatment programmes	
Ruff & Nieman, 1990 (19)	E: cognitive remediation: attention, visuospatial abilities, learning and memory, problem-solving. C: day-treatment programme focussed on psychosocial functioning and activities of daily living.
Christensen 1992 (25)	Group treatment 10-15 persons: Cognitive training, special education lessons, psychotherapy, voice therapy, workshops, physical training, lectures, relatives group.
Rattok et al. 1992 (20)	All three treatment packages: Attention training 80 hours, Community activities 60 hours. E1: Cognitive remediation 120 hours, Small-group interpersonal exercises 100 hours, Personal counselling 40 hours. E2: Cognitive remediation 0 hours, Small-group interpersonal exercises 200 hours, Personal counselling 60 hours. E3: Cognitive remediation 200 hours, Small-group interpersonal exercises 0 hours, Personal counselling 60 hours.
Teasdale et al. 1993 (26)	Group treatment 10-12 patients: cognitive therapy, speech and language therapy and psychotherapy (individual and group), special education when required and physical exercise. Relatives group sessions twice a month.
Malec 2001 (27)	Most group treatment according to model of Prigatano and Ben-Yishay and others. General goals: self awareness, coping and compensation skills, personal organization, emotional and behavioural self-management, participation in work and leisure activities, health maintenance.
Cicerone et al. 2004 (21)	ICRP: structured and integrated individual and group treatment; cognitive remediation, increasing awareness; interpersonal communication; psychotherapy; family support; work trials and placements. SRP: primarily physical, occupational, speech and neuropsychological therapies determined to individual needs. Some recreational, educational, or psychological counseling when needed.

Treatment characteristics: duration/intensity	Treatment team	In- or out-patient
Duration 198.9 days. Intensity: 254 hours therapy	Staff-patient ratio not specified. Treatment team: neuropsychology, physiatry, neuropsychiatry, OT, cognitive therapy, social work, ST, PT, nurses.	Inpatient
Duration: E and C both 8 weeks four days a week Intensity: 36 h. E daily 1 h group therapy, 3 h cognitive remediation and 20-30 minutes wrap-up session. C daily 1 h group therapy, 3 h psychosocial functioning and activities daily living and 20-30 minutes wrap-up session.	Staff-patient ratio and treatment team not specified.	Outpatient
Duration /intensity: Phase 1: 4 months group treatment 4 days a week for 6 h per day. Phase 2: monthly group meeting. Furthermore coordination of gaining employment, education and disability pensions. Intensity not specified.	Staff -patient ratio not specified. Treatment team: neuropsychologist, clinical psychologist, special education teacher, ST, voice therapist, PT.	Outpatient
Duration /intensity: 400 hours during 20 consecutive weeks 5 h per day 4 days per week. Those judged by staff to be viable for work trials were assigned to vocational counsellor. Vocational trials ranged from 12 weeks to 6 months. Actual job search and placement was initiated by vocational counsellor. Patients were followed up indefinitely on work status and general adjustment. Some were placed immediately after remedial phase without work trials.	One psychologist per two patients. Staff -patient ratio not specified.	Outpatient
4-5 months group treatment 4 days a week for 6 h per day. Followed by 6 months contact and meetings with emphasis on return to work or educational environment.	Staff-patient ratio and treatment team not specified.	Outpatient
Duration: Graduates: 189.5 days (27.07 weeks) Dropouts: 43.4 days (6.2 weeks) Intensity not specified.	Staff-patient ratio not specified. Treatment team: neuropsychologist, OT, OT-assistant, PT, recreational therapist, rehabilitation nurse, social worker, speech pathologist, vocational counsellor, physiatrist.	Outpatient
Duration ICRP 3.8 months. ICRP 4 days per week 5 h per day (typically 15 h therapy per week) + one day per week work trial. Intensity: about 248 therapy and 116 work h. SRP initially 15 h per week and adjusted varying form 12-24 h per week. Intensity not specified. Duration SRP 3.9 months.	ICRP Staff-patient ratio not specified. Treatment team: not described, vocational therapist supervises work trials. SRP: Staff-patient ratio not specified. Treatment team: PT, OT, neuropsychological therapists, recreational therapist, vocational/educational therapist, psychological counsellor.	Outpatient

Table 4. **Intervention characteristics** (continued)

Author, Year (Ref)	Intervention
Sarajuuri et al. 2005 (22)	E: Interdisciplinary neuropsychologic rehabilitation and psychotherapy based on Christensen, Prigatano, Ben-Yishay. C selection from patients seen for neuropsychological examination with previous conventional clinical care and rehabilitation (in- and outpatient).
Hashimoto et al. 2006 (23)	Group treatment: brain injury education, social skills training, positive behavioural support, redesigning subject's environment.
Cicerone et al. 2008 (18)	ICRP: integrating interventions for cognitive deficits, emotional difficulties, interpersonal behaviours and functional skills within a therapeutic community with performance feedback and active self-evaluation. Individual (4 h) and group (11 h) therapy. SRP: individual interdisciplinary treatment, primarily discipline-specific interventions. Physical, occupational, and speech therapies. One hour neuropsychological treatment. Some patients psychological, recreational, vocational or educational. Individual (≥12 h) and group (≤3 h) therapy.

C = control; **E** = experimental; **ICRP** = Intensive Cognitive Rehabilitation Programme; **OT** = Occupational therapy; **PT** = Physical therapy; **ST** = Speech and language therapy; **SRP** = Standard Neurorehabilitation.

Discussion

This systematic review of the effectiveness of comprehensive rehabilitation programmes for chronic patients with severe brain injury identified 13 relevant articles that fulfilled pre-established minimal criteria for internal validity. Seven studies used comparative designs of which only 2 were RCTs. These RCTs (18, 19) were both directed at day-treatment programmes showing positive effects on daily life functioning and community integration. The effectiveness of the day-treatment was substantiated by 4 controlled, comparative studies (20, 21, 22, 23) and 3 uncontrolled longitudinal cohort studies (25, 26, 27). The positive effects after treatment were maintained in all 4 studies with a follow-up (18, 25, 26, 27). Residential treatment also led to changes in daily life functioning and social participation, but this was shown by only one comparative study (24). The effectiveness of residential treatment was substantiated by 2 cohort studies (28, 29) showing positive effects of these treatment programmes on daily life functioning, community integration and employment. The functional gains were maintained at one-year follow-up (24, 29). Only one study (30) investigated a neurobehavioral treatment programme showing improved functioning in several life areas (living accommodation, employment, hours of care needed) that was maintained at follow-up.

Treatment characteristics: duration/intensity	Treatment team	In- or out-patient
5 days per week 8.30-16.00 per day. Intensity not specified. Duration 6 weeks. Afterwards neuropsychologic follow-up support and coaching in work or education. C no active treatment.	E: Staff-patient ratio not specified. Treatment team: 3 neuropsychologists, neurologist, rehabilitation nurse, social worker, 2 ST, OT, PT. Consultations by neuropsychiatrist, neuroradiologist and physiatrist. C: no active treatment.	E Inpatient C previous inpatient / outpatient
4 groups with different duration/intensity varying from 4x4 h per week for 6 months to 2 h for 2 days per week for 3-4 months	Staff-patient ratio not specified. Treatment team: doctor, nurse, social worker, clinical psychologist, ST, vocational rehabilitation counsellor, OT, welfare facility life advisor, PT, rehabilitation gymnastic trainer.	Outpatient
ICRP + SRP Duration: 16 weeks. Intensity: 15 h per week therapy = 240 hours.	ICRP Staff-patient ratio not specified. Treatment team: not described, neuropsychologist. SRP: Staff-patient ratio not specified. Treatment team: PT, OT, ST, neuropsychological therapist, recreational therapist, vocational/educational therapist, psychological counsellor.	Outpatient

The first research question concerning the effectiveness of the comprehensive programmes for treating long-term psychosocial problems in patients with severe acquired brain injury cannot be answered adequately based on the current literature. Generally, it may be stated that daily life functioning and community integration can be enhanced by comprehensive programmes, with the highest level of evidence for the effectiveness of day-treatment programmes. However, for each of the 3 programme types, more qualitatively high-level research needs to be performed. Yet, in severely behaviourally disturbed patients, RCTs are difficult to perform because a control treatment may be unethical or unacceptable to caregivers. In these cases, cohort studies using a waiting period as a control condition may be an alternative to provide more evidence on the effectiveness of comprehensive programmes.

All treatment programmes included relatively young and predominantly male brain injury patients, most of whom had severe TBI, which is in accordance with TBI population rates. In general, the inclusion criteria for the treatment programmes were merely marginally described: baseline cognitive and behavioural functioning were specified only in 2 studies (29, 30) while other patient characteristics were not described at all. As a consequence, it must be concluded that the specific patient characteristics for the different comprehensive treatment programmes are still not known. In order to accumulate evidence in this field, researchers must elaborate carefully on the patient characteristics in future work. With this information we

will be able to identify prognostic personal factors for positive outcomes. This, in turn, may contribute significantly to the treatment efficiency.

There appeared a large heterogeneity in the intervention characteristics between different (types of) programmes. The neurobehavioural treatment and the residential treatments were inpatient programmes for subjects with severe behavioural difficulties and functional disabilities, respectively. Whereas the neurobehavioural programmes aimed to restructure psychosocial behaviour, the residential community reintegration interventions were directed specifically at improving functional abilities. The day-treatment programmes offered neuropsychotherapy in group programmes to patients in whom behavioural problems might be present, but only mild. The duration of treatment was different in the 3 types of programmes. The neurobehavioural programme lasted more than one year, the residential community reintegration programmes lasted between 6 months and one year, whereas the day-treatment programmes varied in length from 1.5 months to 6.2 months. These differences partly answer our third research question concerning the essential intervention characteristics of the various programmes. More specific characteristics cannot be given due to the limited description of the content, intensity and duration of the programmes.

The conclusions of this review are generally in agreement with those of Cicerone (8, 9) and Turner-Stokes (10). The additional value of this review is, however, the clear distinction between types of comprehensive treatment programmes and the focus on patient and intervention characteristics. It underscores the necessity to provide more detailed information about these characteristics in future studies in order to be able to compare them adequately. Furthermore, compared with previous work (8-10), it integrates a larger number of studies concerning comprehensive rehabilitation in the chronic phase of severe acquired brain injury. However, the results of this review do not justify straightforward recommendations for clinical practice due to the limited methodological quality of the included studies and the heterogeneity of the interventions. The review does, however, reflect the present situation and clearly highlights the shortcomings and gaps in the present literature and knowledge of comprehensive treatment programmes for severe chronic brain injury.

Implications for future research

Given the present lack of high-quality studies, well-designed controlled studies (preferably RCTs) are necessary to further enhance the field of comprehensive treatment programmes for patients with severe acquired brain injury. Although performing an RCT in this area is notoriously difficult, this review shows that, at least in the field of day-treatment programmes, RCTs are possible. When treating

patients with severe behavioural disorders in the chronic phase, other ways to control bias appear to be justified, such as using a waiting period before enrolment in the treatment arm. In all types of controlled studies, researchers are strongly encouraged to work according to the CONSORT Statement checklist, describing the general principles of a RCT (12-16) even when using a non-randomized design. In the same way as for pharmacological trials, the treatment characteristics should be described in detail, including dosage, duration and means of administration (32). The same is true for patient inclusion and exclusion criteria, in order to be able to compare different studies reliably. Editors and reviewers should be very strict in requiring that all studies provide this descriptive information.

Outcomes should always be presented as absolute scores and effect sizes with parameters of central tendency and variation. Effectiveness must be measured with responsive instruments validated in patients with brain injury in the chronic phase. For instance, the CIQ that was used in 5 of the 13 studies in this review is reliable and responsive (33) and is recommended to assess community integration objectively (34). And the World Health Organisation Quality Of Life Assessment Abbreviated (35) is a well validated and responsive instrument for brain injury patients (35). The Centre for Epidemiologic Studies-Depression Scale is a valid instrument to measure mood in this population (36) and the McMaster Family Assessment Device is a reliable and valid tool to measure family functioning (37). In addition, more individually tailored instruments such as Goal Attainment Scaling can be used (38).

When sound evidence of the effectiveness of different comprehensive treatment programmes is available, the next steps should entail the comparison of treatment mixes and testing differences in treatment duration and intensity to determine cost-effectiveness. Lastly, better theoretical underpinning of the interventions seems essential and possible using models from neuropsychology and cognitive psychology as well as knowledge from neurobiological research on severe brain injury, for instance about the impact of diffuse axonal injury (39) on the clinical course of cognitive impairments after severe brain injury. The hypotheses based on these models and neuroscientific information can then be tested to improve the results of comprehensive rehabilitation programmes (40).

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3

A prospective study to evaluate a new residential community reintegration programme for severe chronic brain injury

the Brain Integration Programme

Gert J Geurtsen
Juan D Martina
Caroline M van Heugten
Alexander CH Geurts

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Abstract

Objective: To assess the effectiveness of a residential community reintegration programme for participants with chronic sequelae of severe acquired brain injury that hamper community functioning.

Design: Prospective cohort study.

Subjects: Twenty-four participants with acquired brain injury (traumatic n=18; stroke n=3, tumour n=2, encephalitis n=1). Participants had impaired illness awareness, alcohol and drug problems and/or behavioural problems.

Intervention: A skills oriented programme with modules related to independent living, work, social and emotional well-being.

Methods: The Community Integration Questionnaire, CES-Depression, EuroQOL, Employability Rating Scale, living situation, work status were scored at the start (T0), end of treatment (T1), and one-year follow-up (T2).

Results: Significant effects on the majority of outcome measures were present at T1. Employability significantly improved at T2 and living independently rose from 42% to over 70%. Participants working increased from 38% to 58% and the hours of work per week increased from 8 to 15.

Conclusions: The Brain Integration Programme led to a sustained reduction in experienced problems and improved community integration. It is concluded that even participants with complex problems due to severe brain injury, who got stuck in life, can improve their social participation and emotional well-being through a residential community reintegration programme.

Keywords: community integration, employment, living skills, residential community reintegration programme, neurobehavioral, outcome

Introduction

Brain injury can have a tremendous impact on both the patient and his family. They must learn to live with a lifelong diminished potential for physical, emotional, cognitive, and social functioning (1). Many patients with acquired brain injury succeed in community reintegration after going through hospital care with or without primary acute rehabilitation. However, apart from the direct consequences of injury such as cognitive, affective, emotional, and behavioural problems and an impaired awareness of limitations (2), some patients develop secondary, psychiatric problems later in life. These problems encompass anxiety, depression, and even alcohol and drug dependencies. Through this compilation of serious problems patients may run aground.

Rao et al. (3) presented a review of the psychiatric consequences of traumatic brain injury, indicating that depressive complaints occur in approximately 25% of the patients. Anxiety disorders are also common, ranging from 11 to 70% (4). Furthermore in 5–70% a major behaviour dyscontrol syndrome occurs for which a multidisciplinary approach has been recommended (3). The great variation in prevalence of psychiatric disorders is the direct consequence of the use of different definitions and methods: High scores on questionnaires are not the same as psychiatric diagnoses, but they are often used as equivalents in the literature. Substance abuse with traumatic brain injury increases the risk of poor outcome on different areas such as medical, neurobehavioural, vocational and life satisfaction and is, therefore , a major threat to people with traumatic brain injury (5, 6). The prevalence of substance abuse in this population is unknown, but the number of subjects demonstrating abuse related problems increases in the years post-injury up to 2–3 times the normal population (5).

The ultimate goal of the rehabilitation process after brain injury is to attain optimal community reintegration and a satisfying quality of life including a good balance between social and work functioning considering individual limitations (7). Several post-acute cognitive rehabilitation programmes addressing the long-term consequences of brain injury have been developed (8). In their review, Malec and Basford (9) classified rehabilitation programmes for chronic sequelae of brain injury in:

1. neurobehavioral programmes,
2. residential community reintegration programmes,
3. comprehensive (holistic) day treatment programmes,
4. outpatient community re-entry programmes, and
5. community-based services (as a continuation of care).

Residential community reintegration programmes are especially suitable for patients with the complex psychiatric and/or behavioural problems as described above. These programmes 'provide integrated cognitive, emotional, behavioural, physical, and vocational rehabilitation to patients who cannot participate in outpatient programs either because of severe cognitive and behavioural impairments' (9, p. 198). The Brain Integration Programme (BIP) is such a programme. This programme aims at achieving optimal community integration for these complex chronic participants sometimes years after the brain injury (10, 11, 12). Regional rehabilitation centres offering standard post-acute programmes (comprehensive day treatment programmes or outpatient community re-entry programmes) may refer their severe participants to the BIP as a last resort to prevent them from running aground or from admission to a neuropsychiatry department (13). In addition participants are referred to this programme by neuropsychiatry departments to reach community reintegration for their participants after the neurobehavioural treatment. The BIP is a national well-recognised programme covered by all health care insurance companies in The Netherlands (12).

The effectiveness of residential community reintegration programmes for these complex brain injured participants with psychiatric and/or behavioural problems has only marginally been investigated. Most of the research that has been reported are case studies, yielding promising results (14, 15) or cohort studies investigating factors that predict change (16). Therefore the present study was undertaken as a prospective cohort study to determine whether the residential community reintegration BIP is effective in treating these complex participants. The study is aimed at investigating whether

1. the programme is effective in terms of improved emotional well being, better quality of life, a higher level of community integration and better employability as primary outcomes leading to greater independency in living situation as secondary outcome, and whether
2. the primary and secondary outcomes remain stable over time.

Method

Subjects

All participants who had been referred for treatment to the BIP and who met the inclusion and exclusion criteria for treatment were included in the study. Participants were selected for treatment by means of a semi-structured interview leading to a clinical judgement, according to the following inclusion criteria:

- Brain Injury (traumatic, stroke, tumour, encephalitis, hypoxia)
- Having problems in social areas, emotional disturbances, and labour/work

integration (Global Assessment of Functioning Scale score (GAF) (17) less than 65 (see procedure and measures section)).

The exclusion criteria were the presence of:
- Suitability for other (outpatient) cognitive rehabilitation programmes,
- Severe disruptive behaviour posing danger to other participants or staff,
- Complete lack of problem awareness leading to lack of willingness to change,
- Severe memory problems leading to absent or very limited ability to store new information as assessed by previous neuropsychological tests,
- Severe drug addiction, or in case of mild drug addiction, unwillingness to stop drug abuse.

The treatment programme

The BIP aims at an optimal community integration using a standardized treatment consisting of three modules (see figure 1). The essence of the programme is that participants learn to establish a balance in their daily activities during domestic life, work, leisure time, and social interaction, taking into account the possibilities and limitations of the each participant. A balance is considered to be present when a participant integrates all these activities in his/her life and is still able to surmount unexpected obstacles and hindrances in his/her future life. This balance must be present both in the short and the long term. The key to success is, thus the selection and realisation of an individually balanced activity level with sufficient stability and proper paid attendant care to prevent failures and frustrations in the future.

The ***independent living module*** aims at training specific abilities separately, after which an independent performance of several domestic tasks is pursued. In a (very) structured environment the participant learns to perform the necessary housekeeping abilities step by step and then learns to plan and execute all these tasks together. Gradually the amount of structure and guidance provided is reduced. Eventually the amount and type of (paid) attendant care (18) necessary for the long term is determined (19).
In detail, this module consists of:
- Home cleaning (cleaning room, doing laundry, ironing, etc.),
- Grocery-shopping,
- Cooking,
- Planning and taking care of breakfast and lunch,
- Taking care of day/night rhythm,
- Travelling by public transport,
- Budgeting,
- Administrating (handling of letters, bills, archiving).

The average amount of therapy time spent in this module is estimated at 100 hours per person. The theoretical components of the module are given in small groups, but most of the practical training is provided as individual therapy.

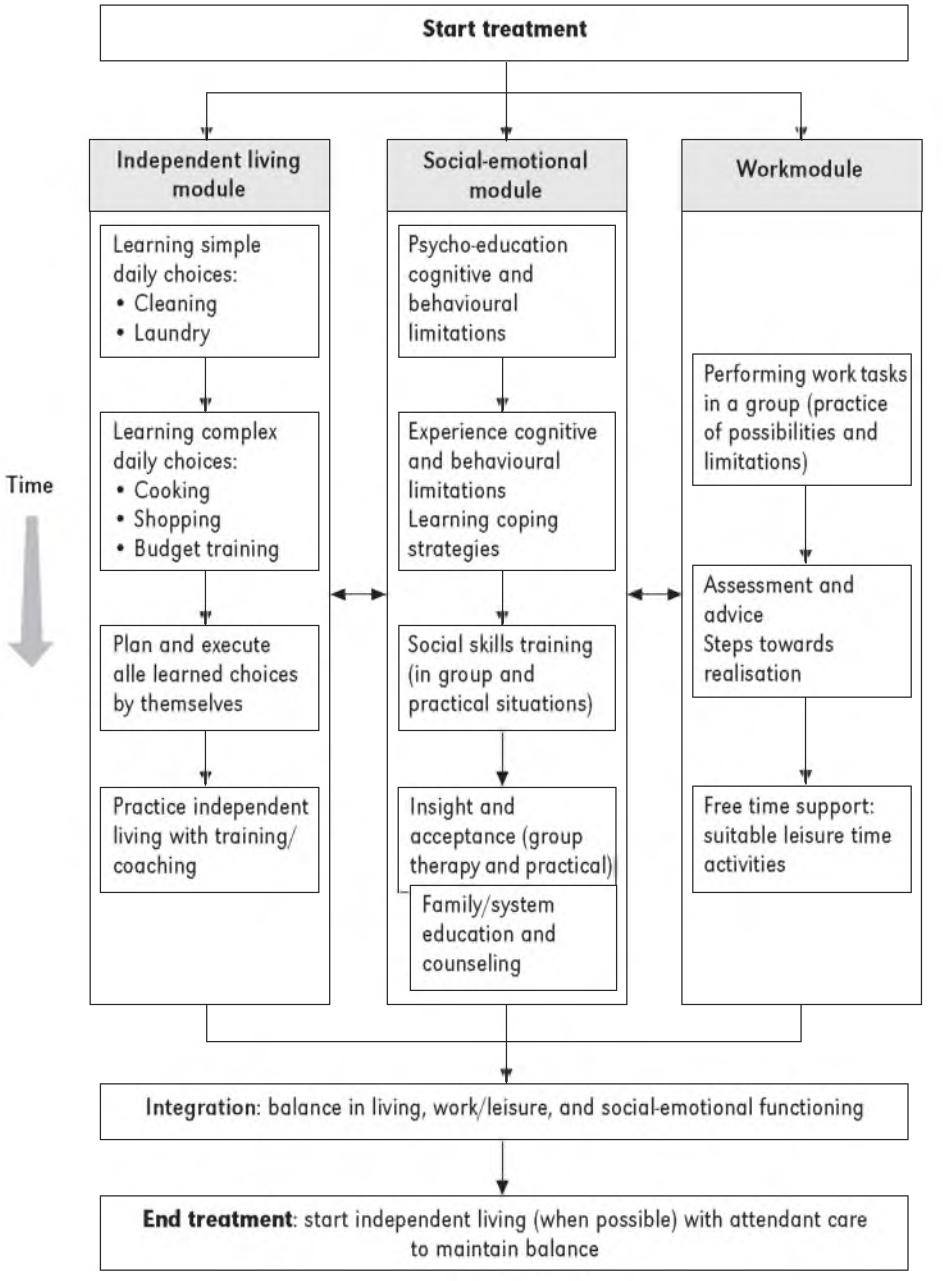

Figure 1. **Modules concerning the three living areas presented the order most often provided. Dependent on participant characteristics the order can be different.**

The ***social-emotional module*** aims at setting new, adjusted and achievable goals in life. Education on brain injury and its individual consequences is given. Moreover, the confrontation during learning and performing practical independent living tasks helps the participant to gain awareness of his/her limitations (20, 21). Developing awareness of one's limitations and gaining insight into the consequences of these limitations for daily life is an important prerequisite for successful reintegration (22). Coping strategies are then trained and counselling is provided to reach a higher level of acceptance. Furthermore, social skills are practised to establish and maintain social contacts and relationships. Similar efforts are directed towards the participant's social system through family education and counselling (23). The aim is to gain a realistic and balanced perspective of personal goals in all areas of life (24).

In detail, this module consists of:

- Education on brain injury and its individual consequences,
- Cognitive training directed at compensation and coping strategies,
- Social skills training with video feedback in groups,
- Day to day feedback and advice on social behaviour,
- Individual counselling to accept limitations and their consequences,
- Group therapy directed at acceptance of long term consequences of brain injury,
- Individual counselling directed at substance abuse prevention,
- Family brain injury education group,
- Individual counselling of relatives to enhance acceptance and to develop coping strategies.

The average amount of therapy time spent in this module is estimated at 110 hours per person. Partly this is done in small groups, but most of the training is provided as individual therapy.

The ***work module*** deals with work and spending leisure time. Participants often have little awareness of their limitations and capabilities due to lack of insight (22). Some are not capable of getting a job or experience failures when working because of executive problems such as poor planning, disinhibition, and poor problem solving (25). When the participant has gained sufficient awareness of limitations during the former two modules the work module can start. First, working tasks are performed in a group to experience individual work limitations and possibilities. Then, in a vocational assessment unit the working-tasks that the participant can perform are determined, as well as the amount of hours he/she can work per week, the necessary adjustments to the workplace, and the personal assistance needed (18). If independent paid work is not achievable alternative possibilities are explored, such as supported or sheltered paid work, volunteer work, or sheltered

activities. In addition, attainable leisure time activities are determined together with the participant.
This module thus consists of:

- Neuropsychological assessment,
- Work practice in groups,
- Evaluation of working abilities in a vocational-assessment unit,
- Evaluation of abilities to perform supported/sheltered work, volunteer work or sheltered activities (when paid work is not possible),
- Free time evaluation and support to give advice about leisure time activities.

The average amount of therapy in this module is estimated at about 44 hours per person. Most of this module is provided as individual therapy.

The programme is provided in a residential setting in one rehabilitation centre in order to realise a safe therapeutic environment for the participants. Continuous feedback is given on behaviour, relating it to the direct consequences for community reintegration. As training progresses learned skills are increasingly applied in daily life. Participants return home every weekend and aquired skills are put into practice at home as well by means of home assignments with support from the rehabilitation team members and relatives. Especially in the social-emotional module relatives are actively involved and supported as well.

The professional staff consists of a neuropsychologist, a physiatrist, a neuropsychiatrist, occupational therapists, cognitive therapists, social workers, speech-language therapists, physical therapists, and rehabilitation nurses/coaches.

Study protocol and measures. A prospective cohort study was conducted with repeated assessments at the start of the treatment (T0), at the end of the treatment (T1), and at follow-up one year after T1 (T2). The study protocol was approved by the regional medical ethics committee.

At T0 demographic and brain injury data such as gender, age, date of injury, aetiology, coma duration, and lowest initial score (<24 hours after trauma/onset) on the Glasgow Coma Scale (GCS) (26) were collected. The Global Assessment of Functioning Scale (GAF) of the Diagnostic and Statistical Manual of Mental Disorders IV (17) determined the impact of problems on functioning. The interviewer scored by the GAF at T0 to determine inclusion for treatment.

The cognitive status of participants was assessed by well-accepted and validated neuropsychological tests at T0: The Test Of Sustained Selective Attention (27), the Trail Making Test (28), The Stroop colour-word test (29), Rey Verbal Learning Test

(30), Story Telling (31), a computerised version of the Tower of London (32), and the Wisconsin Card Sorting Test (33).

At To, T1 and T2 the primary outcome measures were self completed (with an independent interviewer present to assist if necessary):

- Community Integration Questionnaire (34) (CIQ); a 15 item self-report questionnaire consisting of three subscales (Home Integration, Social Integration, and Productivity) and a total score. The total score is used for evaluation. Higher scores indicate higher levels of integration.
- Centre for Epidemiological Studies-Depression (35) (CES-D); a 20 item self-report scale for depression. The higher the score the more depressed the participant is.
- EuroQOL (36); a self-report health related quality of life scale containing a questionnaire with 5 items (EQ-5D) and a Health Status Visual Analogue Scale (EuroQOL Health score). A lower score on the EQ-5D means a better quality of life, and a higher score on the Health score means a better health status.
- Employability Rating Scale (37) (ERS); a one-item scale with 10 categories describing the level of employability. The higher the score the higher the level of employability. The independent interviewer scored this scale.

On a self developed scale an independent interviewer scored:

- Living situation (level of independence and amount of care).
- Active education (attendance at school, hours per week).
- Working status (attendance at work, hours per week and tasks performed).

At To these three scales were scored describing the situation one month before To. At T1 the month after end of treatment was taken as a reference and at T2 the actual situation at that moment was scored. At all times a regular situation was considered (excluding holidays).

Substance abuse was verified through medical records based on clinical impression and by gaining information from relatives at To, T1 and T2 (17).

Statistical analyses. The missing values were corrected with the Yates-formula described by Kirk (38). In this method missing values are corrected by weighing the scores of all subjects on this missing variable and the subject's score on this missing variable on previous measurements.

For the neuropsychological test scores, mean scores and percentiles (based on the mean score) are presented. Participants' scores are considered impaired when they score equal or lower than the 10^{th} percentile.

First, possible differences on the outcome measures between the participants with a time post onset less than a year and those with a time post onset more than a year were considered. If no differences are found, the group is further analyzed in total.

A MANOVA analysis was performed to assess whether there were time effects. This was done for all primary outcome measures together (ERS, CIQ, CES-D, EQ-5D, and EuroQOL Health score). Secondly, post-hoc ANOVA analyses of within-subjects effects with Bonferroni adjustments for multiple comparisons were performed to determine time effects for each individual outcome measure. Pair wise ANOVA analyses were then performed for each outcome measure to determine at what time any effect had occurred. α was set at 0.05 for statistical significance.

Results

Participants

The study group consisted of 24 participants who had sustained either severe traumatic brain injury (75%, n=18), stroke (n=3), a brain tumour (n=2), or encephalitis (n=1). Participants were predominantly male (75%). Other characteristics are shown in Table 1. At T2 data were available from 22 of the 24 participants. One participant refused to cooperate further and one had moved and could not be traced.

Table 1. **Participant characteristics at admission (T0; n=24)**

Variable	Mean (SD)	Range
Age at admission (years)	28.5 (10.3)	17-51
Time since onset (years)	5.4 (7.0)	0.5-31.4
Coma score TBI participants (lowest GCS within 24 hours)	5.9 (1.7)	3-8
Coma duration (days)	15.1 (13.2)	3-42
Living independently (with/without care: n)	10 (41.6%)	
Education (n)	5 (21.0%)	
Work (n)	9 (37.5%)	
Work (hours per week: mean of all 24 participants)	8.1 (14.2)	0-43

GCS = Glasgow Coma Scale; **TBI** = traumatic brain injury.

The cognitive profile of the group of participants is shown in Table 2. Many participants were slow in processing information (TOSSA Speed effect), some had attention deficits (sustained (TOSSA Sustained attention), and selective (TOSSA CS)

and divided attention (TMT B)) as can be seen from the percentage of participants in the impaired range of functioning. In addition, some participants had executive problems (Tower of London, Wisconsin Card). Severe memory problems (REY VLT, Story telling) were infrequent due to the exclusion criteria.

Table 2. **Cognitive profile of the participants at T0**

Variable	Mean score (percentile)	SD	% Participants impaired
TOSSA CS (Concentration Score)	71.9 (10)	23.7	58.3
TOSSA Speed effect on CS (score)	-23.9 (20)	19.0	41.7
TOSSA Sustained attention effect on CS (score)	-8.4 (20)	20.5	33.3
TMT A (sec.)	37.4 (18)	23.2	50.0
TMT B (sec.)	77.9 (27)	39.3	41.7
STROOP card 1 (sec.)	54.1 (5)	16.0	58.3
STROOP card 2 (sec.)	70.8 (8)	20.2	66.7
STROOP card 3 (sec.)	112.3 (14)	39.0	50.0
STROOP Interference (sec.)	41.5 (38)	24.7	25.0
REY VLT immediate recall (nr.)	44.2 (60)	11.3	33.3
REY VLT delayed recall (nr.)	8.7 (60)	3.9	25.0
Story telling immediate recall (nr.)	14.4 (35)	2.9	25.0
Story telling delayed recall (nr.)	13.7 (45)	3.9	25.0
Tower of London (score)	67.3 (30)	10.4	5.9
Wisconsin Card categories (nr.)	4.6 (11-16)	2.2	33.3
Wisconsin Card perseverative errors (nr.)	18.5 (32)	18.0	25.0

TOSSA = Test Of Sustained Selective Attention; **TMT** = Trail Making Test; **STROOP** = Stroop colour-word test; **REY VLT** = Rey Verbal Learning Test; **Wisconsin Card** = Wisconsin Card Sorting Test.

Evaluation of the BIP

The mean duration of the BIP was 198.9 days (range 112–382, SD 71.4). The actual scores on the outcome scales at T0, T1 and T2 are displayed in Table 3. Since there were no significant differences between the eight participants with time post onset shorter than one year compared to those with a longer time post onset on the outcome scales all data are presented as one group.

Table 3. **Scores on primary outcome measures at T0, T1 and T2**

Variable (range)	Mean T0 (SD)	Mean T1 (SD)	Mean T2 (SD)
CIQ (0-29)	14.0 (3.9)	17.2 (5.2)	16.8 (4.6)
CES-D (0-30)	20.1 (13.3)	12.7 (11.2)	15.4 (12.6)
EuroQOL EQ-5D (5-15)	9.5 (1.2)	8.3 (1.6)	8.4 (1.5)
EuroQOL health score (0-100)	60.0 (13.1)	70.9 (16.5)	73.4 (45.1)
ERS (1-10)	2.3 (2.3)	3.2 (2.5)	4.3 (2.5)

T0 = Pre-treatment; **T1** = Post-treatment; **T2** = Follow-up.
CIQ = Community Integration Questionnaire; **CES-D** = Centre for Epidemiological Studies-Depression; **EuroQOL EQ-5D** = Euroqol quality of life scale; **EuroQOL health score** = EuroQOL Health Status Visual Analogue Scale; **ERS** = Employability Rating Scale.

The MANOVA within-subject effect involving time showed a significant time effect for all primary outcome measures together (T^2=4.311, $F_{10,42}$6.035, p=0.002). Post hoc analyses showed significant time effects for each individual outcome measure except the EuroQol health score (see Table 4).

Table 4. **Post-hoc ANOVA analyses**

	ANOVA		
Variable	**F-value**	**Degrees of Freedom F**	**p-value**
CIQ	9.5	2, 46	0.000*
CES-D	7.6	2, 46	0.001*
EuroQOL EQ-5D	9.8	1.9, 43.3	0.000*
EuroQOL health score	1.9	1.3, 29.3	0.183
ERS	10.9	2, 46	0.000*

* p<0.05 with Bonferroni adjustment for multiple comparisons
CIQ = Community Integration Questionnaire; **CES-D** = Centre for Epidemiological Studies-Depression; **EuroQOL EQ-5D** = Euroqol quality of life scale; **EuroQOL health score** = EuroQOL Health Status Visual Analogue Scale; **ERS** = Employability Rating Scale.

Pair wise ANOVA analysis (Table 5) showed a significant increase in community integration (CIQ), a decrease in depression (CES-D) and improved quality of life (EQ-5D and Health score) at T1 compared to T0, without a change between T1 and T2. In contrast the increase in employability was significant between T1 and T2, without a significant change between T0 and T1.

Several participants regained independence and went to live on their own, instead of with their parents (see Table 6). At T1 one participant was living independently and at T2 two participants no longer needed paid care. The rest of the participants who went to live independently still needed some form of support. This support varied from intermittent to partial supervision, with a mean duration of about

6 hours per week. The other participants remained living with their parents or went to a foster home with 24-h supervision. The number of participants working as well as the mean number of hours of work per week increased considerably.

Table 5. **Pair wise ANOVA analysis T0–T1 and T1–T2**

Variable	Mean difference T0–T1	p-value	Mean difference T1–T2	p-value
CIQ	-3.2*	0.001*	0.5	1.00
CES-D	7.4*	0.004*	-2.7	0.61
EuroQOL EQ-5D	1.1*	0.000*	-0.0	1.00
EuroQOL health score	-10.9*	0.013*	-2.5	1.00
ERS	-0.8	0.135	-1.2*	0.03*

* $p<0.05$ with Bonferroni adjustment for multiple comparisons

T0 = Pre-treatment; **T1** = Post-treatment; **T2** = Follow-up.

CIQ = Community Integration Questionnaire; **CES-D** = Centre for Epidemiological Studies-Depression; **EuroQOL EQ-5D** = Euroqol quality of life scale; **EuroQOL health score** = EuroQOL Health Status Visual Analogue Scale; **ERS** = Employability Rating Scale.

Table 6. **Living situation and work status**

	T0	T1	T2
Living independently (with/without care)	10 (41.6%)	18 (75%)	17 (71%)
Living with parents	13 (54.2%)	2 (8%)	5 (21%)
Living in foster home with 24-h supervision	1 (4.2%)	4 (17%)	2 (8%)
Education (# participants)	5 (21%)	4 (17%)	2 (8%)
Work (# participants)	9 (37.5%)	11 (46%)	14 (58%)
Work (hours per week: mean of all 24 participants)	8.0 (SD 14.2)	7.4 (SD 11.2)	15.5 (SD 12.9)

T0 = Pre-treatment; **T1** = Post-treatment; **T2** = Follow-up.

Discussion

Although being an uncontrolled cohort study, this is the first prospective report showing the effectiveness of a residential community reintegration programme on a group level for participants with long lasting complex psychiatric and/or behavioural problems due to brain injury. Improved balance was achieved in all activities of domestic life, work, leisure time, and social interaction, taking into account the possibilities and limitations of each participant. The group investigated

in this study consisted of subjects with brain injury of different aetiologies who got stuck in life due to multiple problems.

Primary outcome

Emotional well-being, quality of life, level of community integration, and employability were the primary outcome measures for which an overall improvement was observed.

Regarding depressive complaints, the level decreased significantly, below the cut-off score for depression (39). The reduction of depression is an important change because it affects many aspects of daily life such as its overall quality (40), occupational activities, and level of independence (41, 42, 43). Apparently, the treatment helped participants to overcome their negative mood. Participants seemed more confident in their future after treatment. It is likely that this improvement can be attributed, directly or indirectly, to the treatment but it cannot be inferred exactly which part of the treatment contributed most to this effect.

With regard to quality of life, participants improved significantly in the areas concerning functioning but less clear-cut in their perceived state of health. The improvement in functioning is in accordance with the training of tasks with regard to independent living. Improvement in health status was not the primary aim of the treatment and can be influenced by many other factors as well.

The community integration score was higher after treatment and remained high at follow up. The rise in this score was substantial considering the complex problems of the participants. The large majority of the participants received no support after acute rehabilitation. Perhaps part of the integration problems might have been prevented when long lasting support had started directly after the brain injury (43).

Employability increased directly after the intervention but did not yet reach significance. This is most likely due to the fact that at the time of discharge the process of finding a suitable job was still ongoing. Indeed, this explanation is confirmed by the significant increase in employability at follow-up. The percentage of participants working was comparable to the results of post-acute brain injury rehabilitation (39–62%) as described by Cicerone et al. (44). This is a promising result considering the complexity of the problems of the participants included in this study. Cope et al. (19) described that employment after brain injury is perhaps the most important outcome characteristic of successful treatment. The fact that some participants find a job even long after treatment has ended underlines the effectiveness of the treatment.

Secondary outcome

Independent living was the secondary outcome variable. Living independently rose to over 70% and remained high at follow-up. This rise of independence is large considering the complex problems of the participants. Such improvement causes a major relief of the burden imposed on relatives and caregivers. Although many participants lived independently at the end of the BIP, most of them still needed paid attendant care, on average about 6 hours per week. Such practical support can helped participants to maintain a good balance between demands and capacities.

At the start of the programme thirty-three percent of the participants had problems with substance abuse. Often such participants are excluded in post-acute treatment programmes or research projects (for instance 45). Because substance abuse can lead to other related problems and disruption of the delicate balance between demands and capacities the reduction of substance abuse is of great importance (5, 6). After the BIP, all participants were no longer abusing drugs and alcohol which result was still present at follow-up.

In general, this study showed significant and clinically relevant improvements in various domains of community functioning as a result of the BIP, a residential community reintegration programme. The reported effect sizes and significances are substantial considering the relatively small number of participants included. Most of the observed improvements were maintained at one-year follow up, which suggests that the programme is effective and leads to stable changes in the long term. This seems quite remarkable for a residential treatment programme after which participants must transfer their learned skills and capacities to everyday life outside the clinic. This indicates that the programme is capable of offering the participants the necessary ingredients to generalize skills to their own daily life situation, which is not a self-evident result. This result can be seen as one of the strengths of the programme. One obvious limitation of this study is the relatively small sample size, however it is, to the best of our knowledge, the first prospective cohort study that provides valuable information on the effectiveness of residential community reintegration programmes for psychiatric and/or behavioural problems due to brain injury. Although there were no differences between the participants with time post onset shorter than one year compared to those with longer time post onset future studies with larger samples should try to identify biological and functional characteristics that can predict outcome, including time post onset. One such study is underway.

As described by Malec and Basford (9) each post-acute brain injury programme has a different emphasis and pursues different goals for participants with brain injury with various residual problems. Their global model is a good start to determine which treatment is best for which participant. A more detailed description of the content of the programmes and participants can help to determine which participant benefits best from which programme. Better operationalization of selection criteria and critical characteristics of participants for whom the treatment is effective can help to clarify treatment interventions in neuropsychological rehabilitation. Such improvements in participant selection can make neuropsychological rehabilitation programmes a more rational endeavour and will promote the understanding and interpretation of research findings. These attempts need to be made in the near future, preferably in larger samples of participants.

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4

A prospective study to evaluate a residential community reintegration programme for patients with chronic acquired brain injury

Gert J Geurtsen
Caroline M van Heugten
Juan D Martina
Antonie CM Rietveld
Ron Meijer
Alexander CH Geurts

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Abstract

Objective: To examine the effects of a residential community reintegration program on independent living, societal participation, emotional well-being and quality of life in patients with chronic acquired brain injury and psychosocial problems hampering societal participation.

Design: A prospective cohort study with a three-month waiting list control period and one year follow up.

Setting: A tertiary rehabilitation center for acquired brain injury.

Participants: Seventy patients with acquired brain injury (46 men; mean age 25.1 years; mean time post onset 5.2 years; at follow up n=67).

Intervention: A structured residential treatment program was offered directed at improving independence in domestic life, work, leisure time, and social interactions.

Main Outcome Measures: Community Integration Questionnaire (CIQ), Employability Rating Scale (ERS), living situation, school, work situation, work hours, Center for Epidemiological Studies-Depression scale (CES-D), EuroQOL quality of life scale (2 scales), World Health Organization Quality of Life Scale Abbreviated (WHOQOL-BREF; 5 scales) and the Global Assessment of Functioning (GAF) scale.

Results: There was an overall significant time effect for all outcome measures (MANOVA T^2=26.16, $F_{36,557}$134.9, p=0.000). There was no spontaneous recovery during the waiting list period. The effect sizes for the CIQ, ERS, work hours and GAF were large (partial η^2 0.25, 0.35, 0.22 and 0.72, respectively). The effect sizes were moderate for 7 of the 8 emotional well-being and quality of life (sub)scales (partial η^2 0.11–0.20). The WHOQOL-BREF environment subscale showed a small effect size (partial η^2 0.05). Living independently rose from 25.4% before treatment to 72.4% after treatment and was still 65.7% at follow up.

Conclusion: This study shows that a residential community reintegration program leads to significant and relevant improvements of independent living, societal participation, emotional well-being and quality of life in patients with chronic acquired brain injury and psychosocial problems hampering societal participation.

Keywords: Chronic Brain Injury; Employment; Quality of Life; Mood; Residential Treatment; Treatment Outcome

Introduction

Acquired brain injury is a significant health problem which often has considerable consequences for societal participation of affected individuals (1). Specifically patients with severe psychosocial problems may experience difficulties with community reintegration. Major adjustment issues as well as problems in transitional periods of living and work situation are frequent and can lead to reduced emotional well-being, depression (2, 3) and decreased quality of life (4). Although employment usually is a predictor of well-being, social integration and quality of life (5-8), too many work hours combined with serious challenges in the home situation can also lead to an emotional overload (9). Hence, the main target for community reintegration programs is to achieve well-balanced improvements in the domains of independent living, employment, emotional well-being and quality of life (10, 11).

Most studies on community reintegration have focused on the sub-acute phase (i.e. less than 1 year) after injury (e.g. Cope et al. (12)). In their meta-analytic review, Rohling et al. (13) found little evidence for the effectiveness of such comprehensive rehabilitation programs when controlling for effect modifiers. Relatively little is known about the effectiveness of community reintegration programs in the chronic phase (i.e. more than 1 year) after injury. In a recent systematic review (14), only three studies of minimal methodological quality were identified concerning chronic acquired brain injury patients. Willer et al. (15) offered a goal-directed intervention in a structured social residential environment based on neurobehavioral principles. They treated 23 chronic patients that were compared with a matched sample of 23 patients receiving limited home-based services. The precise content and intensity of the interventions were not specified. In addition, as acknowledged by the authors, there was no randomized assignment to treatment or control group. Moreover, data of the control group were collected only through the caregivers. Gray and Burnham (16) conducted a historic cohort study using a database of 349 low-functioning chronic brain injury patients, who did not classify for regular rehabilitation. The patients had been offered a multidisciplinary intervention, of which the content was not specified. Admission and discharge data were reported but no follow-up data were available. Geurtsen et al. (11) performed a prospective cohort study of 24 brain injured patients with social, emotional, and vocational integration problems. Patients were treated in a residential community reintegration program consisting of three modules: independent living, social-emotional and work. Admission and discharge data were presented with a follow-up of one year. However, as in the study by Gray and Burnham (16), there was no control of spontaneous recovery or functional change in time. Hence, although all three studies reported functional improvements in various domains of community inte-

gration, employability, living situation, quality of life and emotional well-being, the level of evidence provided by each of these studies was considered low.

In this context, the present prospective cohort study aimed to establish the effectiveness of the Dutch community reintegration program ('Brain Integration Program,' BIP (11)) using a three-month waiting list control period. The waiting list was used to support the notion that treatment effects would not be attributable to spontaneous recovery. We hypothesized that no change would occur during the waiting list period, that significant improvements in the domains of independent living, societal participation, emotional well-being and quality of life would be present directly after the treatment, and that these improvements would be maintained at one year follow up.

Methods

Patients

All patients who had been referred for treatment to the BIP between August 2003 and February 2007 were eligible for the study. Patients were selected by means of a semi-structured interview which was performed by a physiatrist and a neuropsychologist during which inclusion and exclusion criteria were tested (11). Inclusion criteria were:

1. having sustained acquired brain injury (either trauma, stroke, tumor, encephalitis, or hypoxia) at least 6 months ago, proven by CT or MRI;
2. having problems in social functioning, emotional control, and work integration leading to a Global Assessment of Functioning Scale score (17) less than 65; and
3. being 18 years or older.

Exclusion criteria were:

1. suitability for other outpatient cognitive rehabilitation programs;
2. severe disruptive behavior posing danger to other patients or staff;
3. complete lack of problem awareness leading to lack of willingness to change;
4. severe memory problems leading to absent or severely limited ability to store new information; and
5. severe drug addiction or, in case of mild drug addiction, unwillingness to stop drug abuse.

The treatment took place in a tertiary rehabilitation center for acquired brain injury. Rehabilitation centers all over the Netherlands offering 'regular' post-acute care (comprehensive day treatment or other outpatient cognitive rehabilitation programs) referred patients who required more intensive guidance and rehabilitation

due to an abundance of psychosocial problems hampering societal participation, often accompanied by behavioral problems. Although several patients lived independently, this was unsuccessful which often was an important reason for referral. The BIP is a nationally recognized program covered by all health care insurance companies in The Netherlands (18).

All patients gave oral and written informed consent according to the declaration of Helsinki (19). The study was approved by the regional medical ethics committee.

Intervention

The BIP aims at optimal community integration. The essence of the program is that patients learn to establish a balance in their daily activities between domestic life, school and/or work, leisure time, and social interactions, taking into account their individual capacities and limitations (20). An optimal balance is considered to be present when patients integrate all these activities and are still able to surmount unexpected problems. When necessary, this should be accomplished in an adjusted living environment with proper paid attendant care. The BIP is provided in a residential setting within a specialized rehabilitation center for acquired brain injury. It is offered partly in small groups (about 10% of time), but mostly as individual therapy (about 90% of time). After patients are discharged from the program, no follow-up support is given. The treatment program, which has been described more extensively in a previous publication (11), consists of three modules.

The ***independent living module*** aims at training relevant and specific housekeeping abilities. In a structured environment, the patient learns to perform the necessary abilities step by step and then learns to plan and execute all these tasks together in his/her domestic life. The average amount of therapy time spent in this module is estimated at 100 hours per person.

The ***social-emotional module*** aims at setting new, adjusted and achievable goals in life. It encompasses education about brain injury and its functional consequences. Coping strategies are trained and individual counseling is provided to reach a higher level of acceptance. Furthermore, social skills are practiced to establish and maintain social interactions. The average amount of therapy time spent in this module is estimated at 110 hours per person.

The ***vocational module*** deals with work and leisure time. In a vocational assessment unit, the work tasks that the patient can perform are determined, as well as the amount of hours he/she can work per week, the necessary adjustments to the workplace, and the personal assistance needed (21). If independent paid work is not achievable, alternative possibilities are explored, such as supported or sheltered

paid work, volunteer work, or sheltered activities. The average amount of therapy in this module is estimated at about 44 hours per person.

The professional staff for all modules consists of a neuropsychologist, a physiatrist, a psychiatrist, occupational therapists, cognitive therapists, social workers, speech-language therapists, physical therapists, and rehabilitation nurses. The intervention time by the therapists was registered, which did not include the guidance and training by rehabilitation nurses. The latter intervention time was roughly estimated to be 1.5 hours per person per day.

Design

We conducted a prospective cohort study with a three-month waiting list control period and a one-year follow up. Outcome assessments were performed at inclusion (T0), at the start of the treatment three months later (T1), at the end of the treatment (T2), and at follow up one year after finishing the program (T3).

Outcome measures

For societal participation two primary measures were used.

Community Integration Questionnaire (CIQ (22)). The CIQ is a 15-item self-report questionnaire consisting of three subscales (Home Integration, Social Integration, and Productivity). The total score is used for evaluation and ranges from 0 to 29. A higher score represents a higher level of integration. The reliability and validity of the CIQ have been established by previous research (23).

Employability Rating Scale (ERS (24)). The ERS is a one-item scale with 10 mutually exclusive categories describing the level of employability (paid, supported, sheltered etc.). The score ranges from 1 to 10. A higher score indicates a higher level of employability. The ERS was developed for brain injury (24) and has been used in several brain injury studies (e.g. Satz et al. (25)).

In addition to these primary outcomes, the following measures were used as secondary outcomes.

Living situation. The living situation is scored on a one-item scale describing the actual living situation including the amount of care based on the national standard of the Health care indication organization. The scale consists of 12 mutually exclusive categories being:

1. living with parents;
2. residential psychiatric hospital;
3. nursing home;

4. community home (24 hours care);
5. intense home training towards independent living (16–24 hours coaching/supervision);
6. supported independent (12-16 hours coaching/supervision);
7. supervised independent living (9-12 hours coaching);
8. supervised independent living (4-9 hours coaching);
9. living with partner and/or children;
10. living with others;
11. supervised independent living (0–4 hours coaching);
12. living independently without care.

Categories 5–12 were defined as 'living independently,' whereas categories 1–4 were defined as 'not living independently.'

School situation. This dichotomous measure indicates whether patients are attending school.

Work situation. This dichotomous measure reflects whether patients have a paid job.

Work hours per week. Rates the amount of hours per week the patient is working.

For the domains of emotional well-being and quality of life the following outcomes measures were used:

Center for Epidemiological Studies-Depression Scale (CES-D (26)). Emotional well-being was assessed using the 20 item self-report CES-D. The score ranges from 0 to 60 with higher scores representing higher levels of depression. Epidemiological studies found a cut-off score ≥16 for being at risk of depression (27). According to Seel et al. (28), the CES-D has a very good sensitivity but a low specificity in patients with traumatic brain injury (TBI), indicating that it can be used to exclude major depression.

EuroQOL (29). Quality of life was assessed with the EuroQOL, which is a self-report health related quality of life scale containing a questionnaire with 5 items (EQ-5D) and a Health Status visual analogue scale (EuroQOL Health score). The score on the EQ-5D ranges from 5 to 15 with lower scores indicating higher quality of life. The score on the EuroQOL Health score ranges from 0 to 100 with higher scores representing a better health status.

World Health Organization Quality of Life scale abbreviated (WHOQOL-BREF (30)). The WHOQOL-BREF is a 26-item self-report questionnaire, containing two items

for overall quality of life and general health that are combined to one Overall score. The other 24 items are categorized into four domain scores: 'physical capacity,' 'psychological well-being,' 'social relationships' and 'environment.' The Overall score and the four domain scores were used in the analyses. The scores range from 4 to 20 with higher scores indicating higher quality of life. The reliability and validity of the WHOQOL-BREF have been established by previous research (31).

Global Assessment of Functioning Scale of the Diagnostic and Statistical Manual of Mental Disorders IV (GAF (17)). The GAF was used as a clinician's judgment of the individual's overall level of functioning with a range from 0 to 100. A higher score represents a higher level of functioning.

Procedure

At T0 demographic and clinical data such as gender, age, date of injury, etiology, coma duration, and lowest initial score on the Glasgow Coma Scale (GCS (32); <24 hours after trauma/onset; determined by an acute-care paramedic) were collected. The cognitive status of patients was assessed by well accepted and validated neuropsychological tests at T1: Test of Sustained Selective Attention (33), Trail Making Test (34), Stroop Colour-Word Test (35), Rey Verbal Learning Test (36), Story Telling (37), Tower of London (a computerized version (38)), and the Wisconsin Card Sorting Test (39). All neuropsychological tests were performed by an independent test assistant at the rehabilitation center in a quiet room according to the respective test manuals. The CIQ, CES-D, EuroQOL and WHOQOL-BREF were self completed by the patients in the rehabilitation center at T0, T1 and T2 (with an independent test assistant present to assist if necessary). At T3 the CIQ, CES-D, EuroQOL and WHOQOL-BREF were filled in by the patients at home and returned by mail. The same independent test assistant scored the ERS, living situation, school situation, work situation and work hours per week in a face to face interview at T0, T1 and T2 and by a telephone interview at T3. At T0 and T1, scales were scored describing the situation before the assessment. At T2 and T3, the actual situation at that moment was described. At all instants, patients were asked to disregard any holidays from their descriptions of living and work situation. The GAF scale was scored by the same neuropsychologist at all assessments describing the level of functioning at that moment.

Statistical analyses

The characteristics of the patients and the treatment program are presented using descriptive statistics. For the neuropsychological test scores, means and percentiles were determined. Individual patient scores were considered impaired when they were equal to or lower than the 10^{th} percentile based on existing norm scores from the test manuals or test publications. For the neuropsychological tests and the

outcome measures, we examined whether there was a baseline difference between the patients with a time post onset less than one year and the patients with a time post onset more than one year using between-subjects MANOVA (with brain injury less or more than one year as covariate).

A multiple analysis of variance (MANOVA) with Time as a within-subjects factor was done on all non-dichotomous outcome measures together (CIQ, ERS, work hours per week, CES-D, EQ-5D, EuroQOL Health score, 5 WHOQOL-BREF subscales and GAF) to assess whether there was an overall time effect. To determine the effects on each specific outcome measure, we used ANOVA for within-subjects time effects with Sidak adjustments for post-hoc comparisons. Furthermore, the effect sizes were calculated using partial η^2 values. The partial η^2 value was considered small when ranging from 0.05 to 0.1, moderate when between 0.1 and 0.2 and large when greater than 0.2 (40). Next, we performed a pair-wise ANOVA on each outcome measure to determine in what time period significant changes occurred. A Holms procedure was used to correct for multiple outcomes in all Anovas. The two dichotomous dependent variables work situation and school situation, both being categorical variables with two outcomes: change or no change, were analyzed with logistic regression, with time as independent variable.

α was set at 0.05 for statistical significance and p-values were Huynh-Feldt corrected where appropriate. All analyses were performed with SPSS16.

Results

Patients and intervention

Eighty-five patients were referred for treatment of which 70 were included in the study. In Figure 1 the inclusion process is illustrated. At follow up, data were available for 67 (95.7%) of the 70 patients (see Figure 1).

The patients had sustained either a TBI (67.1%; n=47), stroke (10%; n=7), brain tumor (14.3%; n=10), encephalitis (5.7%; n=4), or hypoxia (2.9%; n=2). Forty-six patients were men (65.7%). Subjects had a mean age of 25.1±7.9 years (range 18–49). The mean time post brain injury was 5.2±5.4 years (range 0.5–26.3). Of the patients with TBI, 80% had sustained a 'severe' injury (lowest initial GCS 3–8) and 20 percent had a 'mild' injury (lowest initial GCS 13–15), however, always with concomitant CT or MRI abnormalities, indicating that no patient merely suffered from 'cerebral concussion'. The patient characteristics are shown in Table 1. There were no significant differences between the patients with a time post onset less than one year (n=12) and those with a time post onset more than one year (n=58) on the

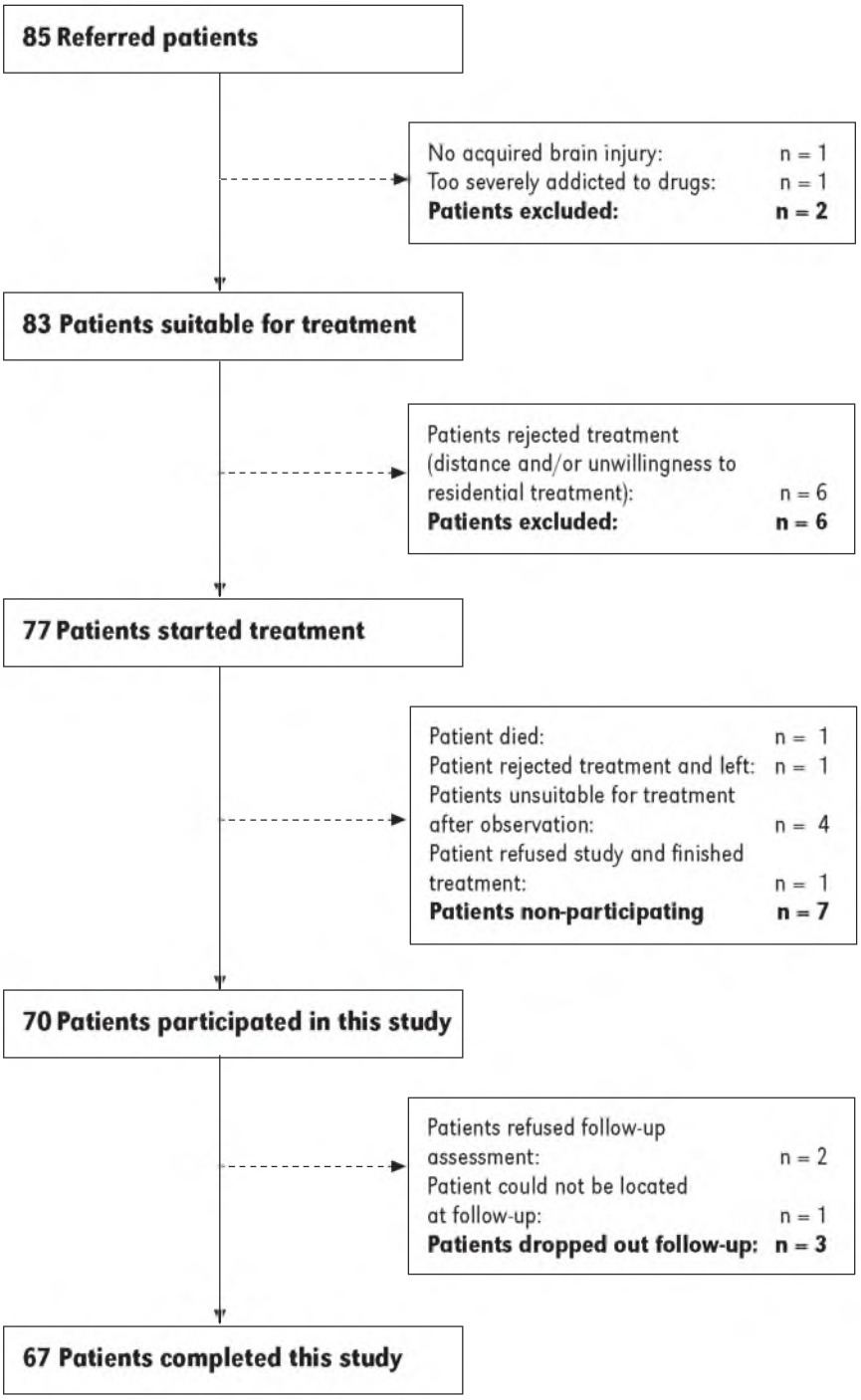

Figure 1. **Flowchart of patient inclusion**

neuropsychological tests and outcome measures. Therefore, the data of all patients are presented and analyzed together.

Table 1. **Patient characteristics at inclusion (n=70)**

	Mean	SD	Range
Age at admission (years)	25.1	7.9	18–49
Time since onset (years)	5.2	5.4	0.5–26.3
Coma score TBI patients (lowest GCS within 24 hours: N=16)	7.5	4.5	3–15
Coma duration* (days)	23.1	30.2	0.5–135
Living independently at T0 (N)	19 (27.1%)		
School at T0 (N)	14 (20.0%)		
Patients at work at T0 (N)	12 (17,1%)		
Work hours at T0 (per week; mean of all patients)	2.5	6.9	0–40

* only TBI patients
TBI = Traumatic brain injury; **GCS** = Glasgow Coma Scale.

Table 2. **Cognitive profile of patients at start of treatment (n=70)**

Test	Mean	SD	% patients impaired
TOSSA CS (Concentration Score)	67.8	24.1	57.8
TOSSA Speed effect on CS (score)	-25.5	17.5	50.0
TOSSA Sustained attention effect on CS (score)	-5.4	23.2	35.9
TMT A (sec.)	47.1	29.7	50.0
TMT B (sec.)	112.5	96.2	42.6
STROOP card 1 (sec.)	57.6	19.0	56.7
STROOP card 2 (sec.)	74.1	23.9	47.8
STROOP card 3 (sec.)	114.9	39.5	28.8
STROOP Interference (sec.)	44.1	26.6	16.7
REY VLT immediate recall (total score)	40.9	12.2	29.0
REY VLT delayed recall (nr.)	7.4	4.8	34.8
Story telling immediate recall (nr.)	14.2	4.2	24.6
Story telling delayed recall (nr.)	12.6	5.0	37.7
Tower of London (score)	76.6	13.5	9.0
Wisconsin Card categories (nr.)	4.8	1.9	32.4
Wisconsin Card perseverative errors (nr.)	17.9	17.1	33.0

TOSSA = Test Of Sustained Selective Attention; **TMT** = Trail Making Test; **STROOP** = Stroop Colour-Word Test; **REY VLT** = Rey Verbal Learning Test; **Wisconsin Card** = Wisconsin Card Sorting Test.

The cognitive profile of the patients is shown in Table 2. As can be concluded from the percentage of patients in the impaired range of functioning, 50% of the patients had a deficit in the speed of information processing (TOSSA Speed effect) and 17–36% had an attention deficit (sustained, selective, or divided attention; TOSSA, STROOP, TMT). In addition, some patients showed executive deficits (Tower of London, Wisconsin Card). Memory deficits (REY VLT, Story telling) were much less frequent.

Table 3. **Mean scores and SDs of outcome measures** (n=67)

Outcome	**T0**		**T1**		**T2**		**T3**	
	M	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
ERS	2.4	2.1	3.1	2.3	4.8	2.8	5.1	2.2
CIQ	13	4.0	13.8	4.5	16.4	4.3	16.8	4.2
Living independently (N)	17 (25.4%)		20 (28.6%)		50 (72.4%)		44 (65.7%)	
School (N)	14 (21.0%)		11 (15.7%)		10 (14.3%)		15 (22.4%)	
Patients at work (N)	12 (17.9%)		11 (15.7%)		23 (32.9%)		36 (53.7%)	
Work hours (only working patients)	14.3	10.8	12.9	16.3	18.1	11.3	18.8	11.2
CES-D	15.49	11.0	14.36	10.7	9.29	7.0	11.48	8.9
CES-D above cut-off* (%)	46.3		43.3		16.4		30	
EuroQOL EQ-5D	9.22	2.0	9.03	1.7	7.99	1.7	8.49	1.7
EuroQOL health score	60.60	18.5	66.81	17.9	76.63	12.3	71.33	17.7
WHOQOL overall	12.33	2.4	13.0	3.5	14.81	2.4	14.26	2.9
WHOQOL physical	13.14	2.7	13.80	3.1	14.98	2.3	14.81	2.8
WHOQOL psychological	12.91	3.0	13.70	3.1	14.65	2.5	14.00	2.5
WHOQOL social	12.57	3.6	13.78	4.1	14.69	3.6	14.21	3.7
WHOQOL environment	14.29	2.6	14.53	2.8	15.40	2.1	15.19	3.4
GAF	47.48	6.9	50.15	8.4	63.10	8.8	65.70	10.1

* cut-off score ≥16

T0 = at inclusion; **T1** = at start treatment; **T2** = post treatment; **T3** = at one-year follow up.

CIQ = Community Integration Questionnaire; **ERS** = Employability Rating Scale; **CES-D** = Center for Epidemiological Studies-Depression scale; **EuroQOL** = EuroQOL quality of life scale; **WHOQOL** = World Health Organization Quality of Life scale abbreviated; **GAF** = Global Assessment of Functioning scale.

The mean duration of the BIP was 196.2 days (SD 61.9; range 44–357; median 199 days).

Outcomes

The means and standard deviations of the outcome measures at T0–T3 are displayed in Table 3 for the 67 patients that completed all assessments. MANOVA showed an overall significant effect of Time for all outcome measures together (MANOVA T^2=26.16, $F_{36,557}$134.9, p=0.000). In addition, ANOVA showed significant time effects for each individual outcome measure (Table 4). The effect sizes for the CIQ, the ERS, the GAF and the work hours were large (partial η^2 0.25, 0.35, 0.72 and 0.22, respectively). The effect sizes were moderate for 7 of the 8 outcome measures concerning emotional well-being and quality of life (CES-D, EQ-5D, EuroQOL Health score, WHOQOL-BREF Overall, physical psychological, social) ranging from 0.11 to 0.20. The effect size for the WHOQOL-BREF environment was small (partial η^2 0.05; see Table 5). The effect sizes for patients with a time post onset less than one year and for those with a time post onset more than one year were comparable (see Table 5).

Table 4. **ANOVA of within-subjects time effects**

Outcome	F value	Degrees of Freedom	P-value
CIQ	22.3	2.8, 187.9	0.000*
ERS	34.9	2.8, 183.6	0.000*
Work hours per week	18.4	2.5, 164.7	0.000*
CES-D	10.5	2.7, 180.8	0.000*
EuroQOL EQ-5D	8.2	2.9, 192.3	0.000*
EuroQOL health score	16.8	3.0, 198.0	0.000*
WHOQOL Overall	12.3	2.9, 192.6	0.000*
WHOQOL physical	11.8	2.8, 185.0	0.000*
WHOQOL psychological	7.30	2.5, 165.8	0.000*
WHOQOL social	7.49	2.9, 192.0	0.000*
WHOQOL environment	3.12	2.5, 165.6	0.036*
GAF	166.6	2.6, 173.8	0.000*

* p<0.05 with Holm's procedure, Huynh-Feldt corrected p-values where appropriate

CIQ = Community Integration Questionnaire; **ERS** = Employability Rating Scale; **CES-D** = Center for Epidemiological Studies-Depression scale; **EuroQOL** = EuroQOL quality of life scale; **WHOQOL** = World Health Organization Quality of Life scale abbreviated; **GAF** = Global Assessment of Functioning scale.

Table 5. **Partial η^2 values of within-subjects time effects**

Outcome	All patients (n=67)	Patients with time since onset <1 year (n=12)	Patients with time since onset >1 year (n=58)
CIQ	0.25	0.24	0.27
ERS	0.35	0.35	0.35
Work hours per week	0.22	0.24	0.22
CES-D	0.14	0.05	0.20
EuroQOL EQ-5D	0.11	0.03	0.15
EuroQOL health score	0.20	0.26	0.21
WHOQOL overall	0.16	0.10	0.18
WHOQOL physical	0.15	0.14	0.16
WHOQOL psychological	0.10	0.13	0.13
WHOQOL social	0.10	0.03	0.17
WHOQOL environment	0.05	0.23	0.03
GAF	0.72	0.69	0.73

CIQ = Community Integration Questionnaire; **ERS** = Employability Rating Scale; **CES-D**, = Center for Epidemiological Studies-Depression scale; **EuroQOL** = EuroQOL quality of life scale; **WHOQOL** = World Health Organization Quality of Life scale abbreviated; **GAF** = Global Assessment of Functioning scale.

Pair-wise ANOVA (Table 6) showed that there were no significant changes in the outcome measures during the waiting list period, except for the GAF that showed a slight but significant increase. A stable baseline was present even in the patients (n=12) with a time post onset less than 1 year. Concerning societal participation significant changes were found immediately after treatment for the CIQ and ERS. Logistic regression showed a significant effect of time on work situation (Wald=23.976, df=1, p=0.000). The chance to remain in the same work situation had decreased by about 50% (Exp(B)=0.517). There was no effect of time on school situation (Wald=0.020, df=1, p=0.888, Exp(B)=0.981). After treatment 72.4% of the patients were living independently compared to 25.4% before treatment.

As for work hours, there was a positive trend in the expected direction, but no significant change was observed immediately after treatment. Yet, the number of patients working at follow up was 36 out of 67 (53.7%) compared to 17.9% before treatment. Work hours per week showed an increase towards 18.8 hours per week on average. Significant and substantial improvements were found after treatment for the CES-D, EQ-5D, EuroQOL Health score, GAF and for the WHOQOL-BREF Overall. As for the other WHOQOL-BREF subscales ('physical,' 'psychological,' 'social' and 'environment') there were only positive but insignificant trends in the expected direction.

None of the outcome measures showed significant deterioration at follow up compared to post treatment.

Table 6. **Pair wise post-hoc comparisons for T0–T1, T1–T2 and T2–T3**

Outcome	T0 – T1	P-value	T1 – T2	P-value	T2 – T3	P-value
CIQ	-0.81	1.000	-2.60	0.000*	-0.42	1.000
ERS	-0.70	0.936	-1.72	0.000*	-0.30	1.000
Work hours per week	0.35	1.000	-3.65	0.072	-4.49	0.087
CES-D	1.5	1.000	5.05	0.000*	-2.30	0.853
EuroQOL EQ-5D	0.2	1.000	1.05	0.008*	-0.51	0.853
EuroQOL health	-6.21	0.803	-9.82	0.000*	5.29	0.853
WHOQOL Overall	-0.75	1.000	-1.73	0.008*	0.54	0.969
WHOQOL physical	-0.65	1.000	-1.18	0.072	0.17	1.000
WHOQOL psychological	-.079	0.803	-0.96	0.246	0.66	0.949
WHOQOL social	-1.22	0.528	-0.90	0.246	0.47	1.000
WHOQOL environment	-0.24	1.000	-0.86	0.246	0.21	1.000
GAF	-2.67	0.026*	-12.96	0.000*	-2.60	0.686

* $p<0.05$ with Sidak adjustment and Holm's procedure

T0 = at inclusion; **T1** = at start treatment; **T2** = post treatment; **T3** = at one-year follow up.

CIQ = Community Integration Questionnaire; **ERS** = Employability Rating Scale; **CES-D** = Center for Epidemiological Studies-Depression scale; **EuroQOL** = EuroQOL quality of life scale; **WHOQOL** = World Health Organization Quality of Life scale abbreviated; **GAF** = Global Assessment of Functioning scale.

Discussion

The goal of this prospective cohort study, using a three-month waiting list control period, was to examine the effectiveness of a residential community reintegration program on the domains of independent living, societal participation, emotional well-being and quality of life in patients with chronic acquired brain injury and psychosocial problems hampering societal participation. The results as well as the maintenance of treatment effects at one year follow up confirm the effectiveness reported in an earlier uncontrolled cohort study (11). The stability of the outcome measures at the two assessments before the intervention supports the notion that the included patients did no longer show spontaneous recovery. This is in accordance with our expectation based on the chronic nature of the brain injury, but appeared to be true even for the 12 patients with a time post brain injury less than one year (range 6 months to one year). Hence, we conclude that the observed effects are most likely attributable to the treatment itself.

With regard to community integration, there was a significant increase in the CIQ after treatment with a slight further improvement at follow up. This effect is comparable to our previous study (11). In a case-control study of a community reintegration program in patients with TBI (15) the CIQ was also used, but raw scores after treatment were not reported. In this latter study, the CIQ score was 10.9 before treatment and appeared to be just below 14 after treatment as assessed from a graph, which is somewhat lower than in our study. Cicerone et al. (41) reported an equally low CIQ score (13.2) in a randomized controlled trial (RCT) of a holistic neuropsychological day-treatment program in patients with TBI, although in an earlier study (42) they reported CIQ scores comparable to our results. Notably, the significant improvements on the CIQ in the present study were relatively small, yet they were larger than those reported in Cicerone's studies (41, 42). This seems to be a good result given the fact that we included patients who were not deemed suitable for a 'regular' outpatient rehabilitation program.

Both the employability as assessed with the ERS and the work situation showed a significant increase after treatment. The number of patients working showed an increase from 17.9% before treatment to 32.9% after treatment with a further increase up to 53.7% at follow up. The patients already working showed an increase in the amount of work hours at follow up. The mean number of work hours at follow up was 18.8, indicating that most of them worked part-time. These results can be regarded as clinically significant considering the figures reported in a recent systematic review on work participation of patients with brain injury (8). In this review it appeared that, 2 years post injury, only 39.9% of the patients with non-TBI and 40.7% of the patients with TBI had returned to work. Fifty-three percent of our patients working at follow up is, therefore, a rather good result, particularly given the selection of patients with psychosocial problems. The increase in the number of working patients as well as the increase in work hours at follow up further support the long-term effectiveness of the BIP. This is especially true because no treatment was given after dismissal from the program. Since, at follow up, 22.4% of the patients were still at school (and some of them will probably have started working after finishing school), the effects on employability may have been even stronger.

After the treatment, the improvement of independent living was substantial, which was followed by a slight further improvement at follow up. The increase towards 65.7% of the patients living independently can be considered quite satisfactory, although 75% of the patients who were living independently received some form of (paid) attendant care (21).

With regard to emotional well-being, there was a significant decrease in the CES-D score after treatment, indicating a lower level of depressive feelings, with merely a slight but insignificant increase at follow up. This effect is comparable to that found in a previous uncontrolled study (11). The level of emotional well-being increased as well as the number of patients that scored below the cut-off of 16, i.e. not being at risk of depression (28). Although the number of patients scoring ≥16 decreased substantially from 46.3% at baseline to 30% at follow up, this incomplete remission of emotional problems warrants further attention in future studies. As for quality of life, there were significant improvements on most scales during the treatment period, except on some of the WHOQOL-BREF subscales ('physical,' 'psychological,' 'social' and 'environment') that merely showed a positive trend. At follow up, no significant change in any quality of life measure was present, which is coherent with previous results (11). Apparently, the obtained emotional and qualitative benefits from the community reintegration program do not easily subside in the long term, which can probably be understood based on the structural improvements of independent living and societal participation. These improvements indicate clinically relevant changes particularly with regard to living situation, work situation and emotional well-being of the patients.

It has been argued that a higher level of independent living and societal participation might lead to an excessive emotional burden on patients with chronic brain injury (9). However, the observed improvements of emotional well-being and quality of life indicated that such a 'trade off' did not occur in our study. On the contrary, a good balance was achieved between school, work and domestic responsibilities, leaving sufficient time for leisure and social activities. At the end of the program, patients appeared to be aware of their limitations and of the necessity to adjust daily activities to their individual abilities.

Study Limitations

We purposely chose to use a waiting list control period and not to conduct an RCT, which is a methodological limitation. However, in our systematic review (14; p. 109), we have argued that conducting an RCT may not be feasible in a population of brain injured patients with severe psychosocial and participation problems. It was anticipated that using a waiting list condition of equal length as the treatment period, a sham treatment or no treatment at all as a control would not be acceptable for the majority of the eligible patients or their caregivers, leading to many of them refusing participation. Using a three-month waiting list period was considered the most feasible design option to obtain at least some form of within-subjects control, albeit not optimal. An alternative would have been to compare the BIP with another existing and realistic intervention, but this option was considered to be premature in the target population of this study, given the lack of clinical

evidence in this area (13, 14). Nevertheless, future studies should attempt to apply more rigorous types of within- or between-subjects control.

Surprisingly, 20% of the patients with TBI in this study had sustained 'mild' brain injury according to their initial GCS score. Yet, all of them showed CT or MRI abnormalities during further investigation, indicating that they did not merely suffer from 'cerebral concussion'. The fact that they also had persistent psychosocial problems supports the notion that the severity of their brain injury was more severe than was estimated based on the GCS. This finding suggests that the initial GCS score may underestimate the severity of injury in some patients. Indeed, it is well known that the GCS score may sometimes deteriorate in the early days after brain injury (43), which limits the predictive value of the lowest initial (< 24 hours) GCS score.

We did not systematically record the behavioral abnormalities of the individual patients before and after treatment due to the lack of one comprehensive instrument to assess all behavioral problems (44). In future studies, some form of assessment of behavioral problems should, nonetheless, be considered. Another limitation is that the GAF, which is a clinician administered scale, was not recorded blind. As a consequence, its effect size may have been relatively large.

The fact that we studied the effect of an intensive (and thus expensive) treatment program, which might be hard to implement in many countries, may also be considered a limitation. Yet, we believe that the costs of residential community integration programs for brain injured patients with societal participation problems are lower than the societal costs (e.g. healthcare costs, informal care costs and productivity losses) that these patients would create when they would not be treated, especially given their relatively young age. Therefore, future studies should also focus on the socio-economic benefits of residential community reintegration programs in these patients.

Conclusions

Until now, this is the largest prospective study of a residential community reintegration program for patients with chronic acquired brain injury using a waiting list control period. It is shown that such a program is an effective treatment leading to significant improvements of quality of life, emotional well-being, work situation and independent living in patients with chronic acquired brain injury and severe psychosocial problems hampering societal participation. Treatment effects are maintained at one year follow up. The results indicate that the improvements of

independent living and societal participation are not achieved at the expense of emotional stability.

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Supplier

SPSS16 was supplied by SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

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5

Experienced emotional burden in caregivers

psychometric properties of the Involvement Evaluation Questionnaire in caregivers of brain injured patients

Gert J Geurtsen
Ron Meijer
Caroline M van Heugten
Juan D Martina
Alexander CH Geurts

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Abstract

Objective: To examine the psychometric properties (internal consistency, discriminant validity, and responsiveness) of the Involvement Evaluation Questionnaire for Brain Injury measuring emotional burden in caregivers of patients with chronic acquired brain injury.

Design: Inception cohort study.

Subjects: Caregivers of chronic acquired brain injury patients.

Measures: Besides the Involvement Evaluation Questionnaire for Brain Injury, the Family Assessment Device and the General Health Questionnaire were used.

Methods: Ninety-eight caregivers filled out all questionnaires, of which 41 caregivers did this twice, before and after the persons they cared for had started a residential community reintegration programme. Cronbach's α and Intra class Correlation Coefficient were calculated for internal consistency. Pearson correlation coefficients were used for discriminant validity and Intra class Correlation Coefficient and Cohen's d were calculated to determine responsiveness.

Results: The internal consistency of the Involvement Evaluation Questionnaire for Brain Injury was good (α=0.73–0.84; Intra class Correlation Coefficient=0.69–0.76). As expected, low correlations were found between the Involvement Evaluation Questionnaire for Brain Injury and either the General Health Questionnaire (r= 0.11–0.40) or the Family Assessment Device subscales (r=−0.29–0.19). Regarding responsiveness of the Involvement Evaluation Questionnaire for Brain Injury, a moderate effect size was found (Cohen's d=0.36) while the Intra class Correlation Coefficient was good (0.80).

Conclusions: The Involvement Evaluation Questionnaire for Brain Injury measures the experienced emotional burden in caregivers of patients with chronic acquired brain injury and seems to be a promising new instrument with good internal consistency, discriminant validity and responsiveness.

Keywords: brain injury, caregiver burden, validity, measurement instrument, assessment

Introduction

Brain injury has considerable consequences for family and other caregivers of the patients. High levels of experienced burden can lead to deterioration in caregivers' health status, social life and well-being (1, 2). Furthermore, a high degree of caregivers' burden can have negative effects on the well-being of persons with brain injury and on the outcome of their rehabilitation (2). Not so much caring for the patient, but the continuous sense of responsibility for and concerns about the brain injured person lead to experienced burden. In this perspective, experienced burden is to a large extent an emotional construct.

Rehabilitation programmes addressing the patients' level of functioning and participation can reduce the level of emotional burden on the caregiver (3). In order to evaluate the effectiveness of treatment on the caregivers we need valid and responsive measures for caregivers' emotional burden. However, such measures are lacking (4). In contrast, several questionnaires have been developed to evaluate the practical burden of care, for instance the Caregiver Strain Index, the Caregiver Reaction Assessment and the Sense of Competence Questionnaire (5). Moreover, proof of responsiveness is lacking in most of these caregivers' questionnaires (5, 6), such as the Sense of Competence Questionnaire and the Caregiver Strain Index, or has not been conclusively demonstrated, such as for the Caregiver Reaction Assessment (5).

Only in mental illness populations a valid and reliable questionnaire was developed, the Involvement Evaluation Questionnaire (7), as a self-report scale to measure emotional burden. Therefore, we decided to test the Involvement Evaluation Questionnaire in the brain injury population. For this purpose we slightly adapted the Involvement Evaluation Questionnaire into the Involvement Evaluation Questionnaire for Brain Injury. However, one cannot assume that the psychometric characteristics of the original Involvement Evaluation Questionnaire, as established in mental illness populations, are the same in brain injured patients. Therefore, the goal of this study was to determine the internal consistency, validity and responsiveness of the Involvement Evaluation Questionnaire for Brain Injury in caregivers of patients with chronic acquired brain injury.

As in the mental illness populations (4), it is not possible to test concurrent validity of the Involvement Evaluation Questionnaire for Brain Injury, because no other instruments measure the same construct. Hence, in the present study, we have chosen to test discriminant validity using related constructs such as family functioning and caregivers' mental health.

The first construct relates to healthy or unhealthy functioning (8). According to many researchers, family functioning is a rather stable characteristic which is related to both physical and psychiatric disorders (8, 9, 10). Yet, unhealthy family functioning can lead to a diminished tolerance of family problems, which may indirectly influence caregivers' burden. Therefore, we hypothesised that family functioning would show only a low association with experienced emotional burden ($r<0.50$).

Caregivers' mental health problems can have several causes (11). Wijngaarden et al. (12) found significant mental health problems only in a subgroup of caregivers of schizophrenic patients who experienced a high degree of burden. This finding is in accordance with the recently published study by Davis et al. (13), who found that mental health and practical burden are different constructs in caregivers of brain injured patients. Therefore, we hypothesised that caregivers' mental health would show merely a low association with emotional burden ($r<0.50$).

In clinical practice and research, responsiveness of an outcome measure is one of its most important properties. To this end, we tested the Involvement Evaluation Questionnaire for Brain Injury in a group of patients with acquired brain injury who had been admitted to a residential community integration programme (14). We expected that their caregivers would show at least some relief of emotional burden after the patients had started the programme, when compared to the moment of inclusion, as a result of feelings of hope and expectations of treatment effects.

Methods

The Brain Integration Programme is a residential community integration programme for patients with chronic acquired brain injury who show behavioural problems, severe problems in social and emotional functioning, and who experience great difficulties in their vocational integration (14). The inclusion criteria for the treatment are:

1. having sustained acquired brain injury (traumatic, stroke, tumour, encephalitis, hypoxia),
2. having problems in social areas, emotional disturbances, and labour/work integration,
3. unsuitability for other (outpatient) cognitive rehabilitation programmes (14).

In ongoing studies on the effects of this programme, the principal caregivers of all patients who participated during the years 2004 and 2009 were included. In one part of the ongoing studies, concerning the admission period 2004–2007,

the caregivers filled out the questionnaires twice: once after inclusion and the second time after a waiting list period of three months, which served as a control period in the effectiveness study (15). In this study 41 caregivers filled out the same questionnaires a second time, within two weeks after the start of the treatment programme.

The principal caregiver, who was at least 18 years old, was asked to fill out the questionnaires. No additional inclusion criteria were used. Each caregiver filled out the questionnaires immediately when the patient had been selected for the treatment programme. The study was approved by the regional medical-ethics committee.

Instruments

The Involvement Evaluation Questionnaire for Brain Injury (see appendix on p. 103 for the questionnaire items) is a slightly adapted version of the Involvement Evaluation Questionnaire (10). The Involvement Evaluation Questionnaire is an originally Dutch self report questionnaire with 31 items and has been developed to measure caregivers' worries, coping and emotional burden as a consequence of mental illness of patients. The Involvement Evaluation Questionnaire and the Involvement Evaluation Questionnaire for Brain Injury are both scored on a 5-point Likert scale (never, sometimes, regularly, often, (almost) always). The questions concern a period of four weeks prior to the assessment. It takes about 20 minutes to complete the Involvement Evaluation Questionnaire for Brain Injury. Two items contribute to two subscales. The Involvement Evaluation Questionnaire has a sum score based on 27 items and comprises four subscales:

1. Tension (9 items) refers to a possibly strained interpersonal atmosphere.
2. Supervision (6 items) by caregivers of patients' medicine intake, sleep, dangerous behaviours, etc.
3. Worrying (6 items), which covers painful interpersonal cognitions, for instance on patient's safety, health and health care.
4. Urging (8 items), which refers to activities such as stimulating the patient to take care of himself, eat appropriately and undertake sufficient activities.

The subscales were established through a factor analytic study (4). The Involvement Evaluation Questionnaire has been validated in several countries and is available in eleven European languages and in two non-European languages. The original Dutch version of the Involvement Evaluation Questionnaire has good internal consistency, test-retest reliability (4, 7, 16) and is sensitive to change (17).

The Involvement Evaluation Questionnaire for Brain Injury is essentially the same as the Involvement Evaluation Questionnaire, however, the term 'mental health problem' was replaced by 'brain injury problem' in four of the 31 items. This adap-

tation was made in collaboration with the developer of the original Involvement Evaluation Questionnaire (7).

The Family Assessment Device (9, 18) is a widely used self report questionnaire (19) and often applied in brain injury research (8, 20, 21). The Family Assessment Device comprises 60 items and is based on the McMaster model of family functioning and family dynamics. The Family Assessment Device contains seven subscales:

1. Problem solving,
2. Communication,
3. Roles,
4. Affective responsiveness,
5. Affective involvement,
6. Culture and
7. General functioning.

The concurrent and discriminant validity were good (8) and the internal consistency of the subscales was moderate (20). Furthermore, the one week test-retest reliability was moderate as well (10). Cut-off scores were determined per subscale to differentiate healthy from unhealthy families (10). The diagnostic confidence, being the proportion of correctly identified cases compared with expert opinion, was between 0.68 and 0.89 (10).

The 12 item version of the General Health Questionnaire (11, 22) is a widely used self report screening instrument for psychological health in general health care. The General Health Questionnaire is used as case-detector for mental health problems. The General Health Questionnaire had a high sensitivity and high specificity with a Receiver Operating Curve area 0.88 in 5.438 general health care patients (11).

Statistical analyses

Descriptive statistics were used for caregivers' and patients' characteristics. For internal consistency, Cronbach's α and one way Intra class Correlation Coefficients were determined, as was done in the study of the original Involvement Evaluation Questionnaire (4). Internal consistency was considered to be good if Cronbach's α and Intra class Correlation Coefficient were between 0.70 and 0.90 (23). Discriminant validity was tested by calculating Pearson correlation coefficients between the Involvement Evaluation Questionnaire for Brain Injury on the one hand and the Family Assessment Device subscales and the General Health Questionnaire on the other hand. To assess the responsiveness of the Involvement Evaluation Questionnaire for Brain Injury, one way Intra class Correlation Coefficients were calculated using a General Linear Model with repeated measures. In addition, responsiveness was expressed in terms of effect size, using Cohen's d, which was calculated by

$(\mu_1 - \mu_2) / \sigma$, where μ_1 and μ_2 are the mean scores at inclusion and at start of treatment, respectively, and σ is the standard deviation at inclusion. Values from 0.20 to 0.30 were considered a 'small' effect, between 0.30 and 0.80 a 'moderate' effect and greater than 0.80 a 'large' effect (23). All analyses were performed with SPSS16.

Results

Ninety-eight caregivers of patients with acquired brain injury were included simultaneously with the patients that were included in the trial. All caregivers were willing to participate. The caregivers were predominantly female (67.3%; n=66), their mean age was 48 (9.3) years, and most caregivers (80.6%; n=79) were parents (Table 1a). Fifty-nine (60.2%) patients had sustained traumatic brain injury, 14 (14.3%) a brain tumour, 11 (11.2%) a stroke, 10 (10.2%) encephalitis and 4 patients (4.1%) a hypoxia. Patients were predominantly male (69.4%; n=68) and their mean age was 25 (7.8) years (Table 1b). Of the patients with traumatic brain injury, 86% had sustained a severe injury (Glasgow Coma Scale 3–8), 5% a moderate injury (Glasgow Coma Scale 9–12) and 9% a mild injury (Glasgow Coma Scale 13–15).

Table 1a. **Caregivers' characteristics: all caregivers (n=98) and responsiveness sample (n=41)**

	All caregivers	(SD; range)	**Responsiveness sample**	(SD; range)
Age in years	48	(9.3; 22-71)	47.9	(8.2; 25-61)
Relation:		(%)		(%)
Parent	79	(80.6)	33	(80.5)
Spouse	13	(13.3)	6	(14.6)
Child	1	(1.0)	0	(0)
Sibling	3	(3.1)	2	(4.8)
Other family member	1	(1.0)	0	(0)
Friend	1	(1.0)	0	(0)

Table 1b. **Patient characteristics (n=98)**

	Patients	(SD; range)
Age in years	25	(7.8; 15-49)
Time since onset in years	5.7	(6.2; 0.2-26.3)
Lowest GCS score TBI patients within 24 hours	6.6	(3.6; 3-15)
Coma duration in days	24.1	(30.4; 0-135)

SD = Standard Deviation; **GCS** = Glasgow Coma Scale; **TBI** = traumatic brain injury.

Regarding the sum score of the Involvement Evaluation Questionnaire for Brain Injury, Cronbach's α was 0.89 and the Intra class Correlation Coefficient 0.85. As for the subscales of the Involvement Evaluation Questionnaire for Brain Injury, Cronbach's α ranged from 0.73 to 0.84 and the Intra class Correlation Coefficient from 0.69 to 0.76 (Table 2). These values were slightly lower than those of the original Involvement Evaluation Questionnaire (7).

Table 2. **Internal consistency of the Involvement Evaluation Questionnaire for Brain Injury (n=98)**

Subscale	N items	Cronbach's α	Intra class Correlation
Tension	9	0.84	0.76
Supervision	6	0.78	0.76
Worrying	6	0.79	0.73
Urging	8	0.73	0.69
Sum score	27	0.89	0.85

Low correlations were found between the Involvement Evaluation Questionnaire for Brain Injury scales and the Family Assessment Device subscales (r=−0.29 −0.19). Only two of the thirty-five tested correlations were statistically significant, namely Involvement Evaluation Questionnaire-Tension on the one hand and Family Assessment Device Problem solving and General functioning on the other hand. Similar results were found for the Involvement Evaluation Questionnaire for Brain Injury and the General Health Questionnaire (r=0.11−0.40). Four of the five scales of the Involvement Evaluation Questionnaire for Brain Injury showed low, but statistically significant correlations with the General Health Questionnaire (r=0.33−0.40).

Forty-one caregivers filled out the Involvement Evaluation Questionnaire for Brain Injury for a second time within two weeks after the start of the residential treatment programme, which was three months after the assessment at inclusion. The one way Intra class Correlation Coefficient was 0.80 (95% C.I.=0.68−0.88), indicating a good reliability of the change score. Cohen's d effect size was 0.36. The raw scores at start of treatment were lower, meaning less emotional burden, compared to the assessment at inclusion for treatment on the subscales Tension, Worrying, Urging and for the sum score (Table 3).

Table 3. **Raw mean scores Involvement Evaluation Questionnaire for Brain Injury (n=41)**

Scale	Mean at Inclusion	(SD)	Mean at Start	(SD)	Cohen's d
Tension	8.02	(4.91)	6.12	(4.36)	0.39
Supervision	2.00	(2.99)	2.12	(2.87)	-0.04
Worrying	9.12	(4.32)	8.17	(4.68)	0.22
Urging	7.73	(5.76)	5.76	(5.22)	0.34
Sum score[1]	25.32	(14.11)	20.27	(13.50)	0.36

1) Two items are used in more than one scale. The total score therefore differs from the sum of the subscales.
SD = Standard Deviation.

Discussion

The results of this study indicate that the internal consistency of the Involvement Evaluation Questionnaire for Brain Injury subscales was good and comparable to the internal consistency of the original Involvement Evaluation Questionnaire for mental illness populations (4). Furthermore, the responsiveness and (discriminant) validity of the Involvement Evaluation Questionnaire for Brain Injury seem to be good as well. The low correlations between the Involvement Evaluation Questionnaire for Brain Injury and either the General Health Questionnaire or the Family Assessment Device subscales indicate that family functioning and mental health are truly other constructs than experienced emotional burden of caregivers. The Family Assessment Device showed almost no association at all with the Involvement Evaluation Questionnaire for Brain Injury, suggesting that emotional burden is very different from a 'stable' construct such as family functioning (8, 9). Emotional burden is determined by the worries and concerns of the caregiver about the patient. Indeed, a caregiver has to cope with the deficits of the patient as well as with his or her own worries about current and future functioning of the patient. In this perspective, emotional burden may be an 'anticipatory' measure, sensitive to expected changes rather than actual changes in functioning and participation of the patient. The General Health Questionnaire identifies persons with mental health problems (11). Although many caregivers experienced mental health problems, the General Health Questionnaire showed only low correlations with caregivers' emotional burden. These low correlations were statistically significant, however, not clinically relevant. This result is in accordance with the study by Davis et al. (13), who found that caregivers' mental health was not associated with caregivers' practical burden.

As for the responsiveness of the Involvement Evaluation Questionnaire for Brain Injury, the observed moderate effect size corresponds to our expectations, as the start of the treatment programme probably led to feelings of hope, expectation and emotional relief in the caregivers of the patients, irrespective of the (future) changes in patients' functioning. On the subscale Supervision the initial score was already low at inclusion, so that this subscale could hardly show improvement at the start of treatment. However, for the subscales Tension, Worrying, and Urging, the observed improvements all exceeded a 10% change, while the sum score showed a 20% improvement. The results of the current study are comparable to those of Stam and Cuijpers (17) on the original Involvement Evaluation Questionnaire. Hence, the responsiveness of the Involvement Evaluation Questionnaire for Brain Injury seems to be a valuable psychometric quality, especially because data on the responsiveness of existing questionnaires of practical burden of care (5, 6) are still lacking or inconclusive (5).

A limitation of this study is that it did not determine the test-retest reliability of the Involvement Evaluation Questionnaire for Brain Injury. Although this test property was found to be moderate to high for the original Involvement Evaluation Questionnaire (4), we have planned to perform a test-retest reliability study of the Involvement Evaluation Questionnaire for Brain Injury to confirm this finding in the brain injury population. After establishing the test-retest reliability, the responsiveness of the Involvement Evaluation Questionnaire for Brain Injury needs to be further supported by intervention studies. In addition, its construct validity should be further substantiated, for instance by testing the Involvement Evaluation Questionnaire for Brain Injury in different brain injury populations

This study is a first indication that the Involvement Evaluation Questionnaire for Brain Injury has good internal consistency, discriminant validity and responsiveness, making it a potentially sound tool for the assessment of emotional burden of caregivers of patients with chronic brain injury.

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Appendix

Involvement Evaluation Questionnaire for Brain Injury core item list

How often during the past four weeks:	never	sometimes	regularly	often	(almost) always
1. have you **encouraged** your relative/friend to take proper care of her/himself (e.g. washing, bathing, brushing teeth, dressing, combing hair etc.)?					
2. have you **helped** your relative/friend to take proper care of her/himself?					
3. have you **encouraged** your relative/friend to eat enough?					
4. have you **encouraged** your relative/friend to undertake some kind of activity (e.g. go for a walk, have a chat, hobbies, household chores)?					
5. have you **accompanied** your relative/friend on some kind of outside activity, because he/she did not dare to go alone?					
6. have you **ensured** that your relative/friend has taken the required medicine?					
7. have you **guarded** your relative/friend from committing dangerous acts (e.g. setting something alight, leaving the gas on, forgetting to stub cigarettes out)?					
8. have you **guarded** your relative/friend from self-inflicted harm (e.g. cutting himself, excessive medicine intake, suicide attempt)?					
9. have you **ensured** that your relative/friend received sufficient sleep?					
10. have you **guarded** your relative/friend from drinking too much alcohol?					
11. have you **guarded** your relative/friend from taking illegal drugs?					
12. have you carried out tasks normally done by your relative/friend (e.g. household chores, financial matters, shopping, cooking)?					
13. have you **encouraged** your relative/friend to get up in the morning?					
14. has your relative/friend disturbed your sleep?*					
15. has the atmosphere been strained between you both, as a result of your relative/friend's behaviour?					
16. has your relative/friend caused a quarrel?					
17. have you been annoyed by your relative/friend's behaviour?					
18. have you heard from **others** that they have been annoyed by your relative/friend's behaviour?					
19. have you felt threatened by your relative/friend?					

	never	sometimes	regularly	often	(almost) always
20. have you thought of moving out, as a result of your relative/friend's behaviour?					
21. have you been able to pursue your own activities and interests (e.g. work, hobbies, sports, visits to family and friens)?					
22. have you **worried** about your relative/friend's **safety**?					
23. have you **worried** about the kind of **help/treatment** your relative/friend is receiving?					
24. have you worried about your relative/friend's **general health**?					
25. have you **worried** about how your relative/friend would manage financially if you were no longer able to help?					
26. have you **worried** about your relative/friend's **future**?					
27. have you **worried** about your own **future**?					
28. have your relative/friend's brain injury problems been a burden to you?*					
29. have you got used to your relative/friend's brain injury problems?					
30. have you felt able to cope with your relative/friend's brain injury problems?					
31. Has your relationship with your relative/friend changed **since the onset** of the brain injury?					

*) Items used in more than one subscale

Involvement Evaluation Questionnaire for Brain Injury subscale items

Subscale	N items	Item in scale
Tension	9	14, 15, 16, 17, 18, 19, 20, 27, 28
Supervision	6	7, 8, 9, 10, 11, 14
Worrying	6	22, 23, 24, 25, 26, 28
Urging	8	1, 2, 3, 4, 5, 6, 12, 13
Sumscore	27[1]	1-20, 22-28
Coping	4	21, 29-31

1) items 14 and 28 are used in more than one scale.

6

Prospective study of a community reintegration programme for patients with acquired chronic brain injury

effects on caregivers' emotional burden and family functioning

Gert J Geurtsen
Caroline M van Heugten
Ron Meijer
Juan D Martina
Alexander CH Geurts

Revised version submitted to Brain Injury

Abstract

Objective: To examine the effects of a residential community reintegration programme for patients with behavioural problems due to acquired chronic brain injury on caregivers' emotional burden and family functioning.

Design: A prospective cohort study with waiting list control and one year follow-up.

Subjects: Forty-one caregivers of which 28 female. Mean age was 48±8.3 years and 33 caregivers were parents.

Intervention: A structured residential treatment programme was offered to the patients directed at domestic life, work, leisure time, and social interactions.

Measures: The Involvement Evaluation Questionnaire for Brain Injury (IEQ-BI) for emotional burden, the General Health Questionnaire (GHQ) for psychological health, and the Family Assessment Device (FAD) for family functioning were used.

Results: There was an overall significant effect of Time for all outcome measures (MANOVA T^2=9.1, $F_{15,3176}$4.1, p=0.000). The effect sizes were moderate for three IEQ-BI subscales (partial η^2 ranging from 0.12 to 0.17), and small for two subscales (partial η^2 0.05–0.09). The effect size for GHQ was moderate (partial η^2 0.11). As for FAD no significant time effects were present (partial η^2 0.00–0.04).

Conclusions: Emotional burden and psychological health of the caregivers improved significantly when patients with acquired brain injury and behavioural problems followed a residential community reintegration programme. Family dynamics remained stable.

Keywords: chronic brain injury; caregiver burden; rehabilitation outcome; residential treatment

Introduction

Brain injury has considerable consequences for the family and other caregivers of the patients. High levels of experienced burden can lead to deterioration in caregivers' health status, social life, well-being and psychological health (1, 2). Furthermore, a high degree of caregivers' burden can have negative effects on the well-being of the persons with brain injury and their rehabilitation outcome (2, 3).

Research has given us some understanding of the effect of brain injury on the caregivers. It appears that caregivers are likely to benefit from specific treatment (4). In their critical review, Visser-Meily et al. (2) found that counselling had the most positive effects when given individually for at least 8 hours and focused on the problems of the caregivers themselves. However, according to a more recent systematic review on family interventions for brain injury populations, research in this field is still in its infancy and there is not much evidence yet available to formulate recommendations for daily clinical practice (5).

It may be that not so much the physical care for the patient, but the continuous sense of responsibility for and concerns about the brain injured person leads to experienced emotional burden by the caregiver (6). Specifically patients with behavioural problems experience difficulties with community reintegration, which may lead to an emotional burden on their caregivers. Rehabilitation programmes addressing the patients' level of functioning and participation can, thus, reduce the level of emotional burden on the caregivers (3). A community reintegration programme seems to be beneficial for the most vulnerable patients with acquired brain injury (7, 8, 9) and can lead to functional improvements in the domains of independent living, employment, emotional well-being and quality of life (8, 9). In a recent systematic review considering chronic brain injury patients, only three studies were found dealing with the psychosocial effects of residential community reintegration programmes (10). Yet, none of these studies investigated the concomitant effects of the treatment on the caregivers.

Therefore, the aim of this study was to investigate the effects of a residential community reintegration programme on the caregivers. Specific questions were whether the residential community reintegration programme directed at the patients:

1. would be effective in reducing caregivers' emotional burden as well as improving caregivers' psychological health; and
2. would lead to changes in family functioning and family dynamics.

Methods

Participants

As part of a larger study on the effects of the Brain Integration Programme (9), the primary caregivers of all patients admitted between June 2004 and February 2007 were eligible for this study. The patients were selected for treatment using the following inclusion criteria:

1. having sustained acquired brain injury (traumatic, stroke, tumour, encephalitis, hypoxia);
2. having problems in social areas, emotional disturbances, and labour/work integration;
3. being 18 years and older.

Exclusion criteria were

1. suitability for other (outpatient) cognitive rehabilitation programmes;
2. severe disruptive behaviour posing danger to other patients or staff;
3. complete lack of problem awareness leading to lack of willingness to change;
4. severe memory problems leading to absent or very limited ability to store new information; and
5. severe drug addiction or, in case of mild drug addiction, unwillingness to stop drug abuse (8).

The primary caregiver, who was at least 18 years old, was asked to fill out the questionnaires. No additional inclusion criteria were used. The study was approved by the regional medical-ethics committee. All patients agreed upon involving the caregivers, and gave oral and written informed consent according to the declaration of Helsinki (11). The caregivers gave oral consent.

Intervention

The Brain Integration Programme aims at optimal community integration. The essence of the programme is to teach patients to re-establish a balance in their daily activities during domestic life, education/work, leisure time, and social interactions, taking into account their possibilities and limitations (12) and to adjust the environment with proper paid attendant care. The programme is provided in a residential setting in one rehabilitation centre in the Netherlands, serving as a tertiary referral centre. The treatment programme is directed at the patients and described in more detail elsewhere (8, 9). Caregivers are offered individual education about brain injury and its behavioural consequences. They also receive psychosocial support by means of individual counselling, when necessary. If they whish they could attend discussions after team meetings and they received information by the rehabilitation nurses through regular phone calls.

Design and procedure

A prospective cohort study was conducted using a three-months waiting list control period and a one-year follow-up. Outcome assessments were performed at inclusion (T0), at the start of the treatment three months later (T1), at the end of the treatment (T2), and at follow-up one year after the end of treatment (T3). At T0 the caregiver questionnaires were self completed by the primary caregiver while they visited the rehabilitation centre. At T1, T2 and T3 the questionnaires were sent by an independent test assistant and returned by the caregivers, all by mail.

Outcome measures

Outcome measures were selected to assess emotional burden and psychological health on the one hand (research question 1) and family functioning and family dynamics on the other hand (research question 2).

Caregivers' emotional burden Few standardized outcome measures considering caregivers' burden have been developed (5, 13). Information about responsiveness of existing burden-of-care scales is still lacking or inconclusive (13, 14) and, up to now, no gold standard has been developed. For this reason, we used a relatively new instrument, the Involvement Evaluation Questionnaire for Brain Injury (IEQ-BI), which has been adapted for and validated in the brain injury population (13). This scale is an originally Dutch self-report questionnaire with 31 items that has been developed to assess caregivers' worries, coping and emotional burden as a consequence of illness of their relative (15, 16). The IEQ-BI has a sum score based on 27 items and comprises four subscales:

1. Tension, which refers to a possibly strained interpersonal atmosphere;
2. Supervision, given by caregivers of patients' medicine intake, sleep, dangerous behaviours, etc.;
3. Worrying, which covers painful interpersonal cognitions, for instance about patient's safety, health and health care;
4. Urging, which refers to activities such as stimulating the patient to take care of himself, eat appropriately and undertake sufficient activities.

The IEQ-BI showed good validity, internal consistency and responsiveness (13). A lower score represents a lower level of experienced burden.

Psychological health The 12-item version of the General Health Questionnaire (17, 18) (GHQ) is a widely used self-report screening instrument for psychological health in general health care. The GHQ is used as case detector for mental health problems. It showed a high sensitivity and high specificity with an area under the receiver operating characteristic of 0.88 in 5.438 general health care patients (18). A lower score represents healthier functioning.

Family functioning and family dynamics The Dutch version of the Family Assessment Device (19) (FAD) is a widely used self-report questionnaire. The FAD (20) comprises 60 items and is based on the McMaster model of family functioning and family dynamics (19, 21). According to many researchers, family functioning and family dynamics are rather stable characteristics which are related to both physical and psychiatric disorders (19, 21, 22). The FAD contains seven subscales:

1. Problem solving;
2. Communication;
3. Roles;
4. Affective responsiveness;
5. Affective involvement;
6. Culture; and
7. General functioning.

The concurrent and discriminant validity have been shown to be good (21) and the internal consistency of the subscales appeared to be moderate (23). Furthermore, the one week test-retest reliability was moderate as well (22). Cut-off scores were determined per subscale to differentiate healthy from unhealthy families (22) and the diagnostic confidence, being the proportion of correctly identified cases compared with expert opinion, was between 0.68 and 0.89 (22). The FAD General functioning subscale is applied in cross-sectional brain injury research (21, 23, 24). The concurrent and divergent validity of the subscales of the Dutch FAD was moderate to good (21). In this version of the FAD, a higher score represents healthier functioning.

Statistical analyses

The characteristics of the caregivers and the patients are presented using descriptive statistics. A within-subject MANOVA with Time as a factor was first done on all 13 outcome measures together (5 IEQ-BI scales; 7 FAD scales and GHQ) to assess whether there was an overall significant time effect. To determine the effects on specific outcome measures, a significant overall time effect was further analysed with ANOVA using Sidak adjustments for post-hoc comparisons. To determine the effect size, the partial η^2 was calculated for each outcome measure. The partial η^2 was considered small when ranging from 0.05 to 0.1, moderate from 0.1 to 0.2 and large when greater than 0.2 (25). Next, a pair-wise ANOVA was performed for each outcome measure with a significant time effect to determine when the changes occurred. α was set at 0.05 for statistical significance and p-values were Huynh-Feldt corrected where appropriate. All analyses were performed with SPSS17.

Results

Forty-one caregivers of patients with acquired brain injury were included simultaneously with the patients that were included in the Brain Integration Programme effect study. No caregiver refused. At follow up, data were available for 38 (92.7%) of the 41 patients. The caregivers were predominantly female (n=28), their mean age was 48 (SD=8.3) years, and most caregivers (n=33) were parents (Table 1). Of the corresponding patients, 30 patients had sustained traumatic brain injury, 6 brain tumour, 2 encephalitis, 2 hypoxia and 1 patient a stroke. Patients had a chronic brain injury (mean=4.6 years post onset, SD=5.4). Patients were predominantly male (n=27) and their mean age was 23.7 (SD=6.5) years (Table 2). Of the patients with traumatic brain injury 80% had sustained a severe injury (Glasgow Coma Scale 3–8) and 20% a mild injury (Glasgow Coma Scale 13–15), however, always with trauma-related abnormalities on CT or MRI of the brain.

The mean duration of the Brain Integration Programme was 196.2 days (SD=61.9, range=44–357, median=199 days). The hours of participation of the caregivers in the treatment was estimated to be 7.5 hours in total per person.

Table 1. **Caregivers' and patients characteristics (n=41)**

Caregivers	**Mean/n**	**(SD; range)**
Age in years	47.9	(8.3; 25-61)
Relation:		
- Parent	33 (80.5%)	
- Spouse	6 (14.6%)	
- Sibling	2 (4.8%)	
Patients		
Age in years	23.7	(6.5; 18-49)
Time since onset in years	4.6	(5.4; 0.5-26.3)
Lowest initial GCS score TBI patients within 24 hours	7.1	(4.7; 3-15)
Coma duration in days	26.8	(85.3; 0-135)

SD = Standard Deviation; **GCS** = Glasgow Coma Scale; **TBI** = Traumatic Brain Injury.

MANOVA showed an overall significant effect of Time on all 13 outcome measures together (5 IEQ-BI subscales, 7 FAD subscales and GHQ; T^2=9.1, $F_{15,317}$ 64.1, p=0.000). In addition, ANOVA showed significant time effects for 4 of the 5 IEQ-BI subscales (Tension, Worrying, Urging and Sum score) as well as for the GHQ (Table 2). On the FAD subscales, ANOVA showed no significant time effects. The effect sizes for the IEQ-BI subscales Tension, Urging and Sum Score were moderate (partial η^2 0.12, 0.17 and 0.17, respectively) as was the effect size for the GHQ (partial η^2 0.11). The effect sizes for the IEQ-BI subscales Supervision and Worrying were small (partial η^2 0.05 and 0.09, respectively, see Table 3).

Table 2. **ANOVA of within-subjects time effects (n = 38)**

Outcome	F value	Degrees of Freedom	P-value*
IEQ-BI Sum score	7.6	2.1, 77.3	0.001*
- Tension	5.1	2.1, 78.2	0.007*
- Supervision	2.1	1.9, 70.2	0.131
- Worrying	3.5	2.5, 91.4	0.026*
- Urging	7.8	2.6, 97.8	0.000*
FAD General functioning	0.0	2.5, 93.9	0.977
- Problem solving	0.8	2.6, 95.4	0.476
- Communication	0.7	2.6, 97.3	0.552
- Roles	0.5	2.7, 98.9	0.660
- Affective responsive	1.4	2.6, 94.4	0.244
- Affective involvement	0.5	2.3, 86.2	0.652
- Culture	0.2	2.6, 94.8	0.890
GHQ	4.7	2.8, 105.4	0.005*

* $p<0.05$ Huynh-Feldt corrected p-values where appropriate
IEQ-BI = Involvement Evaluation Questionnaire for Brain Injury; FAD = Family Assessment Device; GHQ = General Health Questionnaire.

Table 3. **Partial η^2 values of within-subjects time effects (n = 38)**

Outcome	Partial η^2
IEQ-BI Sum score	0.17
- Tension	0.12
- Supervision	0.05
- Worrying	0.09
- Urging	0.17
FAD General functioning	0.00
- Problem solving	0.02
- Communication	0.02
- Roles	0.01
- Affective responsive	0.04
- Affective involvement	0.01
- Culture	0.01
GHQ	0.11

IEQ-BI = Involvement Evaluation Questionnaire for Brain Injury; FAD = Family Assessment Device; GHQ = General Health Questionnaire.

Table 4. **Pair wise post-hoc comparisons for T0–T1, T1–T2, T2–T3 and T0–T3**

Outcome	T0–T1	P value	T1–T2	P value	T2–T3	P value	T0–T3	P value
IEQ-BI Sum score	6.66	0.010*	0.47	1.000	2.42	0.296	9.55	0.004*
- Tension	2.18	0.016*	0.00	1.000	0.53	0.879	2.71	0.048*
- Supervision	0.132	0.990	0.18	0.998	0.66	0.280	0.97	0.365
- Worrying	1.42	0.125	-0.13	1.000	0.90	0.360	2.18	0.028*
- Urging	2.18	0.063	0.50	0.981	0.84	0.520	3.53	0.001*
GHQ	1.03	0.201	-0.11	1.000	0.95	0.311	1.87	0.016*

* $p<0.05$ with Sidak adjustment

T0 = at inclusion; T1 = at start treatment; T2 = post treatment; T3 = at one-year follow-up.

IEQ-BI = Involvement Evaluation Questionnaire for Brain Injury; FAD = Family Assessment Device; GHQ = General Health Questionnaire.

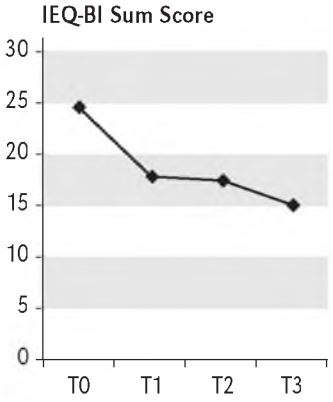

Figure 1.

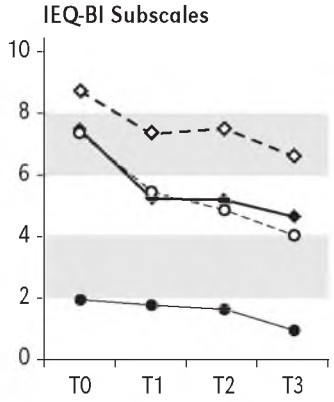

Figure 2.

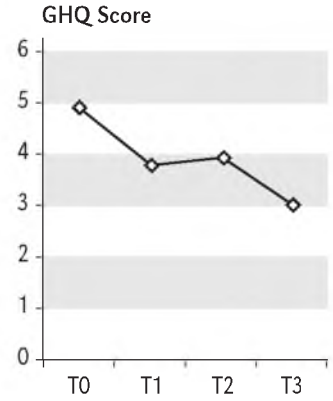

Figure 3.

T0 = at inclusion; T1 = at start treatment; T2 = post treatment; T3 = at one year follow-up.

IEQ-BI = Involvement Evaluation Questionnaire for Brain Injury; GHQ = General Health Questionnaire.

Pair-wise ANOVA (Table 4) showed significant changes at follow-up compared to at inclusion on the IEQ-BI Sum score, Tension, Worrying and Urging and on the GHQ as well. Furthermore, there were significant changes on the IEQ-BI Tension and IEQ-BI Sum score during the waiting list period. No significant change was found immediately after treatment for any outcome measure. None of the outcome measures showed significant deterioration at follow-up. Visual analysis of all IEQ-BI subscales and the GHQ showed a consistent reduction of the scores (see Figure 1-3), indicating a positive effect at follow-up.

Discussion

This prospective cohort study, using a three-months waiting list control period, is the first to examine the effects on caregivers of a residential community reintegration programme (Brain Integration Programme) directed at patients with chronic acquired brain injury with behavioural problems. In a companion paper of this study that reported the effects of the programme on the patients, functional improvements were found in the domains of independent living, societal participation, emotional well-being and quality of life (9).

Emotional burden and psychological health

With regard to emotional burden as well as psychological health of the caregivers, the results showed significant changes at one-year follow-up (T3) compared to the moment of inclusion into the programme (T0). There was a significant decrease in the IEQ subscales Tension and Sum score at the start of treatment compared to the moment of inclusion three months earlier. However, there were no significant changes between the start and the end of treatment. On the GHQ and all IEQ scales slight further improvements were present at follow-up in the expected direction, indicating some additional decrease in emotional burden and better psychological health. It seems that emotional burden and psychological health are determined primarily by the worries and concerns of the caregivers about the patients. Therefore, questionnaires assessing emotional burden and psychological health may be 'anticipatory' measures that are sensitive to expected changes rather than actual changes in patients' functioning and participation (13).

Patients had a chronic brain injury (mean=4.6, SD=5.4 years) and were functioning in a stable (though often suboptimal) situation before inclusion in the Brain Integration Programme. In this perspective, spontaneous changes in the emotional burden or psychological health of the caregivers were not expected. Therefore, the beneficial effects observed after inclusion but before the start of the treat-

ment probably reflect the hopes and expectations of the caregivers rather than actual changes. Of course, these expected changes needed to be translated into actual changes to find stable scores at the end of the treatment. The slight further improvements observed at follow-up further confirm that the expected improvements were indeed realized.

Family functioning and family dynamics

With regard to family functioning and family dynamics the results showed no significant changes. Family functioning and family dynamics are considered to be rather 'stable' constructs (19, 21) that can be influenced by physical and psychiatric disorders (19, 21, 22). This 'stability' might be the reason for the absence of any change. In a recent study on the effect of the Brain Injury Family Intervention, Kreutzer et al. (4) used several outcome measures including the FAD General functioning subscale. They too found treatment effects on several other outcome measures, but not on the FAD. Apparently, the FAD lacks sensitivity as an outcome measure in rehabilitation studies. The FAD was initially selected as an outcome measure based on promising cross-sectional studies (21, 23, 24). However, based on the present study and the study by Kreutzer et al. (4), the suitability of the FAD for longitudinal effect studies seems to be questionable.

Study limitations

The observed effects on the caregivers were relatively small compared to the beneficial effects on the patients (9), which can be explained by the fact that the Brain Integration Programme was primarily directed at the patients. The involvement of the caregivers mainly concerned the improvement of the functioning and behaviour of the patients. This was done by providing them information that focused on the reintegration and behavioural problems of the patients, with little emphasis on the problems of the caregivers themselves. Furthermore, the overall time of caregivers' involvement was limited to about 8 hours. Visser-Meily et al. (2) reported that at least 8 hours of counselling seem to be necessary to obtain any positive effects on caregivers and that counselling should be directed at the problems of the caregivers themselves, not merely on the problems of the patients. Bosschen et al. (5) advised to use active education, skills training and a support-group approach for caregivers of patients with acquired brain injury, because support groups help to address the educational and psychological needs of caregivers. Finally, teaching methods need to become available that aim to adjust the caregivers to the psychosocial consequences of brain injury, to enhance their communication skills, and to help them address their concerns over the future (5). These treatment elements directed at the caregivers themselves were only partly fulfilled in our study. In future studies clearly defined family interventions need to be systematically performed.

Conclusion

A residential community reintegration programme directed at patients with chronic acquired brain injury and subsequent behavioural problems may have concomitant beneficial effects on the emotional burden and psychological health of caregivers. The beneficial effects on caregivers show an earlier time course when compared to the effects on patients indicating an 'anticipation' phenomenon. Future studies should also aim at interventions directed specifically on the problems of the caregivers themselves.

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7

Cost-analysis of residential community reintegration for chronic acquired brain injury
the Brain Integration Programme

Caroline M van Heugten
Gert J Geurtsen
R Elze Derksen
Juan D Martina
Alexander CH Geurts
Silvia MAA Evers

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Abstract

Objective: The objective of this study was to examine the intervention costs of a residential community reintegration programme and to compare the societal costs before and after treatment.

Methods: A cost analysis was performed identifying costs of healthcare, informal care, and productivity losses. We compared the costs in the year before to costs in the year following the Brain Integration Programme (BIP) using the following cost categories: care consumption, caregiver support, productivity losses. For cost valuation Dutch guidelines were used.

Results: Thirty-three cases participated (72% response). Mean age was 29.8 years, 59% traumatic brain injury. The BIP costs were 68,400 Euro. The informal care and productivity losses reduced significantly after BIP ($p<0.05$), while health care consumption increased significantly ($p<0.05$). The societal costs per patient were 48,449 Euro. After BIP these costs were 39,773 Euro; a significant reduction ($p<0.05$). Assuming a stable situation the breakeven point is after 8 years.

Conclusions: The reduction of societal costs after the BIP pleas for the allocation of resources and from an economical point of view favours for the reimbursement of the BIP costs by health care insurance companies. However, this cost analysis is limited as it does not relate costs to clinical effectiveness.

Keywords: brain injuries, cost analysis, rehabilitation, residential treatment, outcome

Introduction

The functional consequences of severe acquired brain injury can have considerable impact on the lives of the patients and their family. The direct consequences of the brain injury are often accompanied by secondary problems in the area of psychosocial functioning (1). The main rehabilitation goal for these persons is to function as independently as possible in their own home and in society (2). The complexity of psychosocial problems in the chronic phase after severe brain injury requires a specialized comprehensive rehabilitation approach. Such approaches can be divided into neurobehavioral programmes, residential community reintegration programmes and holistic day-treatment programmes (3). In a recent review, it was shown that these comprehensive rehabilitation programmes appear to be effective in patients with chronic brain injury in terms of a reduction in psychosocial problems, a higher level of community integration and an increase in employment (4). The evidence is however still limited because the methodological quality of the studies is low. The authors concluded that sound evidence of the effectiveness of the different programmes should become available and that the cost-effectiveness should be determined since these programmes are intensive and therefore costly. Insight in costs is necessary, amongst others, to justify the allocation of scarce health care resources to these programmes.

Economic evaluation in neurorehabilitation is however scarce (5). The few economic evaluation studies looking at the cost-effectiveness of rehabilitation programmes for patients with brain injury have provided some interesting preliminary results. For instance, a Step-up programme in which patients with brain injury resided in a transitional living setting during the last weeks of inpatient rehabilitation, appeared to be more cost-effective than the inpatient alternative (6). Wood et al. (7) assessed the clinical and cost-effectiveness of post-acute community-based social and behavioural rehabilitation for individuals with severe neurobehavioral deficits. In this study, rehabilitation appeared to be cost-effective. Worthington et al. (8) carried out a clinical and cost-outcome evaluation of a neurobehavioral post-acute rehabilitation programme in the UK. Comprehensive and substantial improvements in the life of individuals with brain injury were found. The initial costs of the programme were offset by savings of costs of support in the medium and longer term. A more recent study by Faul et al. (9) showed that the use of clinical treatment guidelines for severe traumatic brain injury resulted in substantial savings in costs and lives (acute care). The majority of cost savings were societal costs. Turner-Stokes (10) investigated the cost-efficiency of longer stay rehabilitation in patients with complex neurological disabilities. The longer stay was offset relatively quickly by long-term savings in the costs of care. And finally Homaifar et al. (11) just recently examined outpatient utilization and costs in a group of vet-

erans with traumatic brain injury. They concluded that a wide array of outpatient services over time was used with a considerable variation in costs. The authors also concluded that further research into economic aspects of care after brain injury is warranted. Moreover, generalized conclusions about the costs of care for persons with brain injury are not possible since the population as well as the forms of care provided are heterogeneous and therefore not comparable. A common element in such research could be to study the societal costs of brain injury. Additionally, as the results of economic studies cannot be generalised from one country to another country-specific studies are needed (12).

The objective of this study was, therefore, to examine the intervention costs of the Brain Integration Programme (BIP) and to compare the costs of patients with acquired brain injury from a societal perspective the year before and the year after following a community reintegration programme in the Netherlands. For this specific programme, i.e. the BIP for patients with chronic acquired brain injury and psychosocial problems hampering societal participation often accompanied by behavioural problems, the effects of treatment have been found to be promising (13) which makes examining the economic aspects an interesting next step.

Methods

Brain Integration Programme (BIP)

BIP is a residential programme that aims at an optimal community reintegration. BIP is offered in a standardized way consisting of three modules: the independent living module, the social-emotional module, and the work module. Patients who are referred for treatment in the BIP are checked for suitability on the basis of a semi-structured interview in which the following inclusion criteria are used: brain injury (traumatic, stroke, tumour, hypoxia, encephalitis), and having problems in social areas, emotional disturbances and community integration (Global Assessment of Functioning score <65 (14)). Patients are excluded from the programme when they are suitable for other (outpatient) cognitive rehabilitation programmes, when they show severe disruptive behaviour, when there is a complete lack of awareness, when they have very severe memory problems or when they are addicted to drugs. Further details about the BIP are given in Geurtsen et al. (13).

Cost analyses

The cost analysis was performed according to the Dutch manual for costing in health care, which is a methodological reference case for performing costing studies in the Netherlands (15, 16). The cost analysis was performed from a societal perspective. This implies that all relevant costs related to brain injury were taken into account disregarding who is bearing the costs.

BIP intervention costs

The BIP costs include hospital days, nursing hours and treatment hours. Overhead and other indirect costs induced by other departments supporting the brain injury department (such as human resources, ICT, planning, outside expertise) are also included in the analysis. For the calculation of the intervention costs micro costing is applied. The cost valuation of the BIP is based on the number of employees, the hours of work per week, the surface in square meters and the number of days of hospitalization. Costs involving personnel and department-specific materials are calculated using a step down method, on average personnel time allocated to each intervention is netted out from time and multiplied using the costs per fulltime equivalent; for all other costs the most applicable distribution formula was used, for instance for maintenance m^2, for food the cost per number of nursing days.

Costs related to brain injury

Cost identification and measurement. The cost analysis involved a comparison of costs related to brain injury in the year preceding treatment in the BIP with costs in the year following treatment in the BIP. The identification of cost categories was based on a literature search, detailed analysis of patient records and interviews with health care professionals of the brain injury department. The following cost categories were identified: care consumption (including medication and aids), caregiver support, and productivity losses. Cost volumes were measured using a cost questionnaire. The cost questionnaire was developed on the basis of interviews with 3 healthcare professionals, 1 economist, and 5 patients. Two questionnaires were developed: one for patients and one for caregivers. The patient version consisted of 67 questions; the primary caregiver version of 77 questions, as the latter also relate to the cost of informal care. Other informal caregivers answered a questionnaire of 19 questions. The questionnaires were divided into a general part, a part investigating the year preceding BIP and a part investigating the situation in the year following BIP. The questionnaires were sent to the home address of the patient. A reminder was sent after 10 days. In case of non-response a telephone interview was offered.

Cost valuation. Care consumption is valued using revised versions of the Dutch Manual for Costing: Methods and Standard Costs for Economic Evaluations in Health Care (15, 16). This guideline produces standard unit costs for The Netherlands. According to this guideline, caregiver support is valued on the basis of the opportunity cost method. This means that the number of hours the caregiver spent on support of the relative with brain injury is valued by means of the income which could normally have been earned during working hours instead of taking care of the patient. The mean income in the Netherlands was 32,000 Euro per year and the mean yearly working time was set at 1356 hours (Statistics Netherlands (17)).

As a result, one hour of caregiver support was valued with an average salary of 24 euro per hour.

Productivity losses were valued with the friction cost method. The basic idea of the friction cost method is that the amount of production lost due to disease depends on the time-span that organisations need to restore the initial production level. In the friction costs, the costs of production lost are equal to the period which is needed to fulfil vacancy. The lost days are valued using average day-wages. All production losses outside the friction period are not valued. During the study the friction period was 22 weeks, this is the time needed to occupy a vacant position. For the valuation of the hours productivity losses within these 22 weeks, also the average salary was used (i.e. 24 euro per hour).

Sample Patients with acquired brain injury who were treated in the BIP were selected in 2005 for analysis when the time of admission to the programme was shorter than three years and the time of discharge was at least one year preceding the start of the study. These dates were chosen to optimize response rates and reliability of the data and resulted in a sample of 46 potential participants.

Sensitivity and statistical analyses

Differences between the data before and after BIP were tested using paired t-tests or Wilcoxon signed rank tests. Differences were only calculated for complete pairs (i.e. patient and caregiver). A sensitivity analysis was performed to check to what extent the valuing of costs was sensitive to change of certain parameters. This was done by examining the (un)certainty of assumptions and conclusions by varying the costs. For the costs prices of the care resources we used CTG tariff instead of standardised cost prices. The CTG tariff is a national declaration tariff defined by the National Health Tariff Authority in the Netherlands (NZA). Furthermore as there is some discussion about the valuation of informal caring time (18), informal caring time was valued using a proxy-good method. The proxy-good method is a straightforward valuation method in which the time spent on informal caring is valued at the shadow price of the most closest related market substitute. In our sensitivity analysis the shadow price of 26.30 Euro per hour (16) was used, which are the costs of a professional care taker in domestic help. In the literature there is some discussion whether productivity should be valued using the friction cost method or the human capital method (19). In the human capital method productivity losses are calculated for the entire period of illness, or from the time of premature death up to the average retiring age (on average 65 years). For all statistical analyses α was set at 0.05.

Results

Response

Forty-six cases could be identified on the basis of the criteria for participation. This means that in total 92 questionnaires were sent out: 46 patients and 46 caregivers. A total of 55 questionnaires were returned (60%); 33 cases (72% of the identified cases) could be included in the analyses of which 7 were involving only the patient (n=29) and 4 only the caregiver (n=26), and in 22 cases both questionnaires of the patient and the caregiver were included in the analysis. The characteristics of the patients and caregivers are shown in Table 1. Patients were mostly men (62%) and most of these had suffered a traumatic brain injury (58.6%). The age at injury was low (mean 24.0 (13.0)). Most caregivers were parents of the patients (73.1%).

Table 1. **Patient (n=29) and caregiver (n=26) characteristics**

Patients	**Mean**	**SD; range**
Gender: M/F: n (%)	18/11	(62.1/37.9%)
Age at admission in years	29.8	10.3; 18–51
Age at injury in years	24.0	13.0; 3–49
Time since onset in weeks	343.9	357.2; 26–1632
Brain injury: n (%)		
– TBI	17	(58.6%)
– Stroke	7	(24.1%)
– Tumour	3	(10.3%)
– Hypoxia	1	(3.4%)
– Encephalitis	1	(3.4%)
Lowest GCS score TBI patients within 24 hours	7.4	3.9; 4–14
Coma duration in days	11.0	11.1; 1–38
Treatment duration in weeks	198.3	77.2; 76–382
Education: low/medium/high: n (%)`	7/18/4	(7.3/62.1/13.8%)

Caregivers	**Mean**	**SD; range**
Gender: M/F: n (%)	7/19	(26.9/73.1%)
Age in years	51.6	10.6; 28–78
Relation to patient: n (%)		
– Parent	19	(73.1%)
– Spouse	4	(15.4%)
– Sibling	1	(3.8%)
– Other	2	(7.6%)
Education: low/medium/high: n (%)	1/19/6	(3.8/73.1/23.1%)

TBI = traumatic brain injury; **GCS** = Glasgow Coma Scale.

Cost analysis. In our analyses we looked separately at the costs of the BIP, furthermore we compared the societal costs the year before and the year after the BIP treatment.

BIP intervention costs. The costs of the BIP were based on direct costs, indirect (overhead) costs and costs for specific expertise. The mean number of hospitalization days was 175. The number of treatment days was 125, because treatment was offered during weekdays. Nursing hours were also calculated only during weekdays. The mean number of treatment hours was 385. The total costs of the programme per patient were 68,400 Euro of which 45,426 Euro was spent on treatment.

Costs related to brain injury. Health care costs were separated into visits to the general practitioner, consulting a specialist, outpatient services, and extramural and intramural care. An overview of these costs the year before and the year after the BIP is shown in Table 2. The number of hours of outpatient services that the patients received per year increased significantly, whereas all other costs decreased (not significantly).

Table 2. **Health care consumption (M, SD) before and after treatment in the BIP**

Health care costs	Before	After	Difference
General practice (number of visits/year)	0.96 (3.43)	0.75 (1.57)	-0.21
Consulting specialist (number of visits/year)	4.2 (11.0)	2.8 (6.1)	-1.4
Outpatient services (number of hours/year)	12 (32)	216 (285)	204*
Extramural care (number of hours/year)	80 (222)	40 (97)	-40
Intramural care (number of hours/year)	37 (95)	23 (85)	-14

Before the BIP 48.5% of the patients used medication. After the BIP this increased to 57.6%. The percentage of patients using memory aids was equal before and after the programme (6.1%) but the kind of aids differed: before the BI patients mostly used laptops and phones whereas after BIP patients mostly used personal digital assistants, which were estimated to be more expensive at that moment. The use of mobility aids reduced slightly after the BIP from 21.2% to 15.2%. Home adaptations were more frequent after the BIP: 6.1% before the BIP compared to 8.4% after the BIP.

The total number of hours of informal care given before the programme was 1030 and after the programme 530; this was a significant reduction of 500 hours ($p<0.05$). The hours were spent on direct care, mobility support and financial, administrative and organisational tasks.

Before attending the BIP the patients worked on average 187 hours per year (3.6 hours per week) while after the programme this had increased to 312 hours (6 hours per week). Before BIP 81.3% of the patients was not working, whereas after the BIP this percentage was reduced to 59.4%. From these results the productivity losses are calculated while taking into account a friction period of 22 weeks: the productivity losses reduced with 1,363 Euro per friction period.

The living situation of the patients changed significantly after attending the BIP ($p<0.05$): after the programme 66.7% of the patients lived independently, with or without support services, whereas 33.3% did so before the programme.

Table 3 gives an overview of the costs per patient in Euro the year before and the year after the BIP. As indicated in this table the health care costs increased after the programme, whereas the costs of informal care significantly decreased. In addition, the productivity losses (non-significantly) diminished after the programme. As a result the total average costs per patient significantly reduced ($p<0.05$). In the year before the BIP the total costs amounted to 48,849 Euro, while the costs in the year after the BIP were 39,773 Euro. In total there is a decrease in costs of 8,676 Euro comparing the two periods.

Table 3. **Average costs in Euro per patient before and after treatment in the BIP**

Brain injury related costs	**Before**	**After**	**Difference**
Health care costs:			
- General practice	19	15	-4
- Consulting specialist	105	70	-35
- Outpatient services	552	9,936	9,384*
- Extramural care	4,000	2,000	-2,000
- Intramural care	7,030	4,370	-2,660
Total health care costs	11,706	16,391	4,685*
Medication and aids:			
- Medication	114	154	40
- Memory aids	26	15	-11
- Mobility aids	223	185	-38
- Home adaptations	7	18	11
Total costs drugs and appliances	370	372	2
Informal care	24,702	12,702	-12,000*
Productivity losses	11,671	10,308	-1,363
Total costs	48,449	39,773	-8,676*

*) $p<0.05$

Sensitivity analyses The sensitivity analysis showed that the results of our analysis were rather robust. Using tariffs instead of standardised cost-prices for the health care costs led to a significant cost difference of 4,945 Euro instead of 4,685 Euro. For informal caring time the use of the proxy good method resulted in a significant cost difference before and after the BIP of –15,383 Euro rather than –12.000 Euro in our original calculation. The use of the human capital method instead of the friction costs methods revealed a non-significant difference of –2,950 Euro instead of –1,361 Euro for productivity losses.

Discussion

The costs analyses of the BIP showed that the intervention costs of the programme were 68,400 Euro per patient. The analyses of the costs related to the brain injury showed that there was a reduction in costs after the BIP of 8.676 Euro per patient. The sensitivity analyses confirmed the robustness of these results. The reduction in costs may have continued further after BIP as the follow up period of one year is probably too short to show all community reintegration effects, especially in terms of return to work.

Assuming that the reduction in costs would remain in the next years, and that this reduction of costs could be assigned to the BIP, it can be opted that the costs of the programme can be earned back after 8 years. The patients in this study were 30 years on average when leaving the programme and have another 35 years to go to the age of 65 (i.e. pensionable age in the Netherlands). Assuming a stable situation in the lives of the patients until the age of 65, this means that the profits of BIP stretch out over a period of 27 years, which would plea for the allocation of resources to BIP and from an economic point of view favours for the reimbursement of the BIP costs by health care insurance companies.

Comparing these results to other findings is difficult because of the heterogeneity in the populations, forms of care and economic aspects which have been studied before. The study by Worthington et al. (8) also concerned the cost analysis of residential rehabilitation programmes for brain injured individuals. They showed that the initial costs of rehabilitation were offset by savings in care costs within 2 years. This is a shorter period than we found, but the savings were restricted to care costs instead of societal costs. Worthington et al. (8) further found that the projected lifetime savings were higher for those who started rehabilitation within 12 months post injury than for the medium and longer term admissions. Wood et al (7) also found greater cost-effectiveness for those who started rehabilitation

within 2 years. These findings suggest that earlier admission to BIP might lead to greater cost reductions as well.

The cost analysis we performed has some limitations. First, we studied a rather small group and we did not compare the costs of the patients attending the BIP with a control group of patients not attending the BIP. Part of the cost reduction could have been caused by the natural course of functioning. We expect this effect however to be small since the mean time since injury was more than 5 years. Secondly, data were gathered retrospectively. Patients had to fill in questionnaires about costs in the past which could be biased, especially in case of brain injury. This bias was reduced as much as possible by asking patients and caregivers both to fill out the questionnaires on the one hand and by asking the psychologist to perform a random check of the questionnaires of the patients on the other hand.

In this study we only looked at the costs related to brain injury and the BIP and we did not investigate the effects. Therefore this study should be seen as a partial economic evaluation. The effectiveness of the BIP was examined in parallel in a prospective design and reported elsewhere (13). Some of the positive effects in terms of community reintegration can also be found in this study: the number of patients living independently as well as the level of productivity increased after attending the programme. We acknowledge the limitations of the present study, but the limited body of evidence on economic aspects of rehabilitation programmes needs to be elaborated further and this study can be seen as a next step in this direction.

In conclusion, the reduction of societal costs after following the Brain Integration Programme justifies the allocation of resources. These costs should be investigated in the long term and related to the clinical effectiveness of the programme in future research.

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8
General discussion

The general aim of the studies presented in this thesis was to describe and enhance the level of evidence on residential community reintegration programmes for patients with chronic acquired brain injury and, more specifically, to study the effectiveness of a Dutch residential community reintegration programme (the Brain Integration Programme (BIP)). The BIP focuses on patients with chronic acquired brain injury who have problems in social functioning, emotional control, and work integration. Rehabilitation centres all over the Netherlands offering 'regular' post-acute rehabilitation programmes refer patients to the BIP who require more intensive guidance and rehabilitation due to persistent psychosocial problems. These psychosocial problems are often accompanied by behavioural problems and hamper societal participation. In this chapter the main conclusions of the studies presented in this thesis are summarized and discussed, together with the strengths and limitations of these studies. In addition, the implications for rehabilitation are given as well as suggestions for future research.

Effectiveness of residential community reintegration programmes on patients

In the literature three forms of comprehensive rehabilitation programmes for patients with chronic acquired brain injury are distinguished (1), i.e. neurobehavioural programmes, residential community reintegration programmes, and comprehensive (holistic) day treatment programmes. However, little is known about the effectiveness of these programmes. Therefore, the main research questions in this thesis concerned the level of evidence for the effectiveness of comprehensive rehabilitation programmes for patients with chronic acquired brain injury. In particular, it was investigated whether there was any evidence in the literature for the general effectiveness of comprehensive rehabilitation programmes (research question 1) and whether the BIP, as a residential community reintegration programme, would produce sustainable effects in the domains of emotional well-being, quality of life, level of community integration, employability and living situation (research questions 2 and 3).

After applying minimal criteria for quality assessment, thirteen relevant articles were identified in a systematic review (chapter 2). Only two studies were randomized controlled trials (RCTs) and both these studies investigated day treatment programmes (2, 3). The conclusions of this review were partly in agreement with previous reviews by Cicerone et al. (4, 5) and by Turner-Stokes (6) on cognitive rehabilitation as well as with a recent systematic review on neurobehavioural programmes (7). Cattelani et al. (7) considered neurobehavioural programmes as mere '**practice options**' for post-injury behavioural disorders. Yet, although they

did not make a distinction between community reintegration programmes and comprehensive day treatment programmes, they considered both these types of programmes as '**practice standards**' for the treatment of patients with acquired neurobehavioural impairments and psychosocial problems. Cicerone et al. (4, 5) regarded comprehensive day treatment programmes as a '**practice standard**' as well. Nevertheless, the systematic review of chapter 2 showed that the level of evidence for all types of comprehensive rehabilitation programmes in patients with chronic acquired brain injury is still rather low, which is in accordance with a recent meta-analysis by Rohling et al. (8). Moreover, it showed that the three forms of comprehensive rehabilitation programmes greatly differed with regard to the duration of treatment. Differences in duration were the only explicit distinction with respect to intervention characteristics among the various programmes. As for patient characteristics, the data collected from the reviewed articles were even more insufficient. As a result, little conclusive evidence appears to be available with respect to comprehensive rehabilitation programmes for patients with chronic acquired brain injury and persistent psychosocial problems. This is particularly true for neurobehavioural and residential community reintegration programmes.

In chapter 4, the effectiveness of the BIP was investigated in a prospective cohort study, implementing two assessments prior to the start of treatment, i.e. before and after a three-months waiting list control period. The stability of the patient-related outcome measures at these two assessments supported the notion that the included patients did no longer show spontaneous recovery with regard to independent living, societal participation, emotional well-being and quality of life. The results of this study indicated that the BIP is an effective treatment leading to significant improvements of quality of life, emotional well-being, work situation and independent living in patients with chronic acquired brain injury and persistent psychosocial problems hampering societal participation. Because all patient-related outcome measures were stable at baseline, improved during the treatment, and remained stable until one year follow up, it is concluded that this study has added to the level of evidence for residential community integration programmes in patients with chronic acquired brain injury.

At the start of this study there were some worries about the possibility that a higher level of independent living and societal participation would lead to an increase in emotional burden on the included patients as suggested by Doig et al. (9). Fortunately, the results of this thesis did not provide any indication for such a trade-off effect between various outcome measures, because improvements in the domains of emotional well-being and quality of life occurred in parallel with improvements in living and work situation. This pattern of results suggests that a good balance was achieved between education, work, and domestic responsibilities on the one hand,

and leisure time and social activities on the other hand. Indeed, such a balance in activities and responsibilities was a main goal of the BIP. Clinical observations by the professional staff indicated that many patients seemed to be made more aware of their limitations and the necessity to adjust daily activities to their individual abilities. This notion was supported by a significant improvement in awareness as measured with the Awareness Questionnaire (10) in a subgroup of 24 of the 70 patients included in the study of chapter 4. Since these data were incomplete, and given the ongoing debate on the definition and theoretical construct of 'illness awareness' in the literature (11), this finding should be interpreted with caution. Further studies are needed to underscore the notion that improved awareness is a relevant underlying mechanism of the beneficial effects of residential community reintegration programmes such as the BIP.

Effectiveness of the Brain Integration Programme on caregivers

It is increasingly recognized that treatment for patients with chronic acquired brain injury should also focus on the needs of the patients' caregivers. In the case of brain injury survivors with prevailing psychosocial and behavioural problems, it seems particularly relevant whether changes in the **emotional burden** on caregivers can be assessed (research question 4). Indeed, the assessment of emotional burden on caregivers in this relatively young population seems to be more relevant than the assessment of caregivers' physical or practical burden, because many of these patients are independent in their basic activities of daily living (ADL). Yet, worries about the practical and societal consequences of persisting cognitive, emotional and behavioural disturbances often lead to continuous emotional distress in proxies (12, 13). In chapter 5, the psychometric properties of the Involvement Evaluation Questionnaire, a scale originally developed to assess caregivers of psychiatric patients, were tested for the first time in a brain injury population (IEQ-BI). It was found that the IEQ-BI had good internal consistency, good discriminant validity and fair responsiveness.

As a matter of consequence, the effectiveness of the BIP was also determined with respect to the emotional burden on caregivers of patients with chronic acquired brain injury (research question 5). In chapter 6, the effectiveness of the BIP on the caregivers' emotional burden, psychological health and family functioning was reported. Both with regard to emotional burden and psychological health, the results showed significant improvements at follow up compared to the moment of inclusion in the programme. However, the time course of these improvements was unexpected. Significant changes already occurred at the start of treatment,

immediately after the three-months waiting list period. Apparently, emotional burden and psychological health of the caregivers improved *in anticipation of* the patients' treatment. It was speculated that feelings of hope and reduction of distress were important underlying mechanisms. The observed stability of the effects at follow up would then reflect the fulfilment of expectations. This hypothesis needs to be confirmed by future studies.

Overall, the results of chapters 5 and 6 provide a first indication that emotional burden on caregivers of patients with chronic acquired brain injury is a relevant construct that can be assessed with the IEQ-BI and that can be influenced by providing patients dedicated and specialized rehabilitation care. However, many more studies need to be conducted to further substantiate these preliminary conclusions.

Cost-effectiveness and long-term effectiveness of the Brain Integration Programme

In addition to its effectiveness, the cost-effectiveness of the BIP should be determined to underscore the societal relevance of the programme (research question 6). In chapter 7, the costs of the BIP were estimated and compared to the estimated societal costs before and after the intervention. It was calculated that the costs of the BIP would be repaid after 8 years by a reduction in the societal costs. Given the relatively young age of brain injury survivors (approximately 30 years in this study) and assuming a prolonged stable situation after treatment, the societal profits of the BIP treatment would, thus, by far outweigh the treatment costs, which would justify the reimbursement of the programme by insurance companies. To further substantiate this notion, the socio-economic benefits of the BIP and other residential community reintegration programmes need to be corroborated by future prospective health economic evaluations.

The study reported in chapter 4 yielded significant beneficial effects directly after the BIP treatment and even slight further improvements of some measures at one-year follow up. In the meantime, additional data have become available concerning the stability of effects until three years after BIP treatment. Out of 70 included patients, the three-years follow up data of 56 patients (80%) who returned questionnaires by mail have now been analysed. Eleven patients did not yet reach the three-years follow up and 3 patients were lost to follow up. Table 1 shows that all outcome measures remained stationary in time, with even small (but insignificant) further improvements of the number of patients with education and employment. Thus, the effectiveness of the BIP appears to be very stable in the long term. Taken into account the steady increase in the numbers of patients working at one- and three-

years follow up, the breakeven point in terms of treatment and societal costs as mentioned above may even be reached earlier than 8 years after the programme.

Table 1. **One- vs. three-years follow up of patients after BIP treatment (n=56)**

Outcome measure	One year follow up		Three year follow up		T-test
	Mean	SD	Mean	SD	p-value
Living independently (%)	65.5%		66.1%		0.722
Education (%)	21.8%		25.0%		0.642
Employment (N)	30 (53.2%)		39 (67.9%)		0.874
ERS	4.80	2.3	5.20	2.6	0.159
CIQ	16.76	4.4	17.29	4.4	0.369
Work hours (all patients)	18.17	11.4	18.14	9.2	0.258
CES-D	11.50	8.8	11.06	8.5	0.696
WHOQOL Overall	14.26	2.7	14.72	2.8	0.329
WHOQOL physical	14.77	2.8	14.83	2.9	0.864
WHOQOL psychological	13.94	2.5	14.58	2.8	0.087
WHOQOL social	14.23	3.6	14.44	3.7	0.601
WHOQOL environment	15.02	3.5	15.77	3.0	0.227

CIQ = Community Integration Questionnaire; **ERS** = Employability Rating Scale; **CES-D** = Centre for Epidemiological Studies-Depression scale; **WHOQOL** = World Health Organization Quality of Life scale abbreviated.

Strengths and limitations

The studies reported in this thesis have several strengths. They encompass one of the first prospective studies on residential community reintegration programmes using a form of within-subjects control by means of a waiting list period. As a consequence, this study significantly contributed to the (limited) evidence of such programmes for patients with chronic acquired brain injury available in the literature. Besides the use of subjective self-report questionnaires, independent assessors established treatment effects with regard to more objective outcomes such as work and living situation. In addition, treatment effects were assessed from the perspective of the caregivers (emotional burden, psychological health) and society (costs).

One of the limitations of the studies reported in this thesis is the absence of a systematic registration and description of the behavioural problems of the included patients. Although the assessment of behaviour using one comprehensive instru-

ment is very difficult due to the variety of possible abnormalities (14), a more accurate description of the observed problems would have enhanced the understanding of some of the mechanisms underlying the beneficial effects of the BIP treatment as described in this thesis. In addition, it might have become more clear which individual behavioural abnormalities would be directly related to the brain injury and which might only be indirectly related. Indeed, behavioural problems may also result from culminating failures and frustrations experienced by patients as a consequence of their cognitive and emotional deficits (15).

Another, methodological limitation is that only a form of within-subjects comparison was applied, preventing the blinding of assessors (and possibly patients) and allowing less stringent control of (unknown) time effects than in randomized controlled trial (RCT) comparing between-subjects effects. Nevertheless, the applied design was selected for several reasons:

- the low level of current evidence in the literature;
- the absence of an alternative treatment;
- the ethical objections against a 'no treatment' condition;
- the relatively long treatment duration of the BIP;
- the estimated risk of large-scale refusal to participate in an RCT, given the emotional strain on both patients and caregivers.

As for the effectiveness of the BIP, a programme evaluation was conducted which prevented the attribution of the observed beneficial effects to specific components of the intervention. With respect to the effects of the BIP on caregivers, only preliminary results could be reported due to the lack of well validated and sensitive instruments. Lastly, the cost-effectiveness was based on estimation of treatment and societal costs rather than on the prospective calculation of real costs over the years.

Implications for rehabilitation

One of the keys of successful community reintegration programmes for patients with chronic acquired brain jury is the achievement of an individually balanced activity level within a sufficiently structured environment with proper paid attendant care, when necessary. Therefore, during and after the BIP treatment, great emphasis is laid on environmental adaptations. As described in the literature, such adaptations generally concern (16, 17, 18):

- provision of a low-stimulus environment when necessary (e.g. by putting objects in fixed places and order of use);

- facilitation of daily tasks by reducing distraction, providing visual cues, and making simple action plans;
- detailed provision of information to caregivers, friends and colleagues about specific problems of the individual patient;
- use of specific tools (e.g. (electronic) diaries, day planners, mobile phones or palm tops).

In addition, it is important to adjust the level of education and vocational responsibilities, to reduce the number of work hours, and to provide a job coach or home support whenever patients are unable to manage the daily demands on their own.

To implement these environmental adaptations, the patients must learn to accept the limitations in their existing level of functioning as well as in their future perspectives. In order to reach sufficient acceptance, individual awareness of the functional impact of the brain injury needs to be developed. To this end, patients have to be regularly confronted with the changes and losses in their capacities. This repeated confrontation is different from the 'errorless learning approach' as proposed by Kessels et al. (19). This latter approach is useful for 'declarative' learning of detailed and factual information, but is probably less appropriate for 'procedural' learning.

To be successful in patients, caregivers need to be actively involved in the treatment. Besides providing them with information, some interventions should specifically focus on the problems of the caregivers themselves. Essential ingredients of such interventions appear to be 'active education' and 'skills training' (20). In particular, it seems important to teach caregivers how to adjust to the psychosocial problems of the patients, to enhance their communication skills, and to help them address their concerns over the future (21).

Although in the prescription and reimbursement of physical rehabilitation an increasing emphasis is laid on short and intensive treatments (22), the studies in this thesis showed that a more prolonged treatment duration may still be necessary to achieve relevant cognitive, emotional and behavioural changes and improved awareness in patients with persisting psychosocial problems after acquired brain injury.

This may also be true for young adults with brain injury acquired at birth who experience similar community integration problems. Some of their psychosocial problems may only become manifest during early adulthood due to increasing demands from society, a phenomenon referred to as 'growing into deficits' (23, 24). It would be ethical, and probably cost-effective, if selected subjects with 'congenital'

brain injury could also profit from the medical, psychological and societal merits of residential community reintegration programmes.

Suggestions for future research

Moving on the slippery slope of science, progression is only made in small steps. The most important next step to be taken in the research area of comprehensive rehabilitation programmes for patients with chronic acquired brain injury is to further enhance the level of methodological control. This could be done by implementing a much longer waiting period before treatment in a within-subjects design (e.g. of equal length as the treatment period), but it would be more optimal to control for (unknown) time effects and patient and assessor bias in a randomized group design focusing on between-subjects effects.

Forthcoming studies should also take into account the effects of rehabilitation interventions on caregivers. Indeed, the current knowledge of the effectiveness of comprehensive rehabilitation programmes on the caregivers of patients with chronic acquired brain injury is very limited (21).

Concerning outcome assessment, a core set of valid, reliable and sensitive instruments should be developed to measure the effects of comprehensive rehabilitation programmes on both the brain injured patients and their caregivers (25). This would promote the comparability of studies and the possibility to perform meta-analyses (8). Besides self-report questionnaires, more 'objective' outcomes should be collected, e.g. opinions of caregivers and other 'stakeholders', because such evaluations are less affected by the awareness problems of the patients (26). In addition, the assessment of real-life changes in e.g. living and work situation is meaningful and valid. Besides at the 'overall efficacy', future studies should focus on the underlying mechanisms of improvements, both in the patients and their caregivers, e.g. by implementing valid and sensitive psychological or neurophysiological measures. This would include relatively new psychological constructs such as 'awareness' (27, 11), 'emotional attention' (28) and 'social cognition' (29). More knowledge of these constructs might enhance our understanding of the complex psychosocial and behavioural problems after brain injury and lead to a better theoretical underpinning of rehabilitation after acquired brain injury.

Conclusion

The studies presented in this thesis have enhanced the level of evidence on residential community reintegration programmes for patients with chronic acquired brain injury who suffer from persistent psychosocial problems hampering societal participation. More specifically, they have shown the (cost-) effectiveness of a Dutch residential community reintegration programme, i.e. the Brain Integration Programme. Future high quality studies are needed to further substantiate the (cost-) effectiveness of residential community reintegration programmes for brain injured patients and their caregivers. Preferably, a fixed core set of outcome measures should be used in these studies to promote meta-analysis of results in the long term.

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9
Summary

The general aim of the studies presented in this thesis was to describe and enhance the level of evidence for residential community reintegration programmes and, more specifically, to study the effectiveness of a Dutch residential community reintegration programme (The Brain Integration Programme (BIP)). The BIP provides integrated cognitive, emotional, behavioural, physical, and vocational rehabilitation to patients in the chronic phase after acquired brain injury who are not able to participate in 'regular' outpatient programmes due to limitations in social functioning, emotional control, and work integration, often accompanied by behavioural problems. The essence of the programme is that patients learn to re-establish a balance in their daily activities with respect to domestic life, work, leisure time, and social interaction, taking into account their individual capacities and limitations. To achieve this aim, the arrangement of an optimally adapted environment is of utmost importance.

In **chapter 1**, the outline and goals of this thesis were presented.

To determine the level of evidence for the effectiveness of comprehensive rehabilitation programmes for patients with chronic acquired brain injury, a systematic review was conducted which was described in **chapter 2**. This review had three objectives. The first objective was to determine the effectiveness of the three forms of comprehensive rehabilitation programmes that are distinguished in the literature (i.e. neurobehavioural programmes, residential community reintegration programmes, and comprehensive (holistic) day treatment programmes). The second objective was to assess whether patient characteristics differed between specific programmes. The third objective was to explore the essential differences in intervention characteristics between these programmes. Thirteen articles were identified that fulfilled pre-established (minimal) quality criteria. Nine studies concerned comprehensive (holistic) day treatment programmes, of which two studies were randomized controlled trials (RCTs), four were controlled comparative studies, and three were uncontrolled longitudinal studies. Three studies concerned residential community reintegration programmes, of which one was a controlled comparative study and two were uncontrolled longitudinal studies. As for the neurobehavioural programmes, only one uncontrolled longitudinal study was found. Due to the limited number of studies and their generally weak methodological quality, the overall effectiveness of comprehensive programmes for treating psychosocial problems in patients with chronic acquired brain injury could not be determined. It was, nevertheless, tentatively concluded that daily functioning and community integration can be enhanced by comprehensive programmes, with the highest level of evidence for the effectiveness of day treatment programmes. The demographic and injury-related data in the reviewed articles were insufficient to differentiate the treatment programmes according to specific patient characteristics. As for

the intervention characteristics, the three types of programmes greatly differed with regard to the duration of treatment. The neurobehavioural programme lasted more than one year, the residential community reintegration programmes lasted between 6 months and one year, whereas the day treatment programmes varied in length from 6 weeks to 6 months. Due to the limited description of the content and intensity of the programmes, no other systematic differences could be identified. As a result, specific treatment programmes could not be related to specific patient profiles. It was recommended that future effect studies on comprehensive rehabilitation programmes for patients with chronic acquired brain injury should use some form of within- or between-subjects control and should clearly describe relevant patient characteristics (e.g. demographic, clinical and functional descriptors) as well as detailed intervention characteristics.

In **chapter 3**, the BIP was described in detail including treatment intensity, treatment duration and staff involved. The BIP uses a standardized treatment protocol consisting of three modules:

1. independent living;
2. social-emotional functioning; and
3. work.

The average amount of intervention time was estimated at 100 hours per person for the 'independent living' module, 110 hours per person for the 'social-emotional' module, and 44 hours per person for the 'work' module. The complementary guidance and training by rehabilitation nurses was roughly estimated to be 1.5 hours per person per day. The mean duration of the BIP was 196 days. We reported a prospective cohort study concerning 24 patients. Outcome measures were the Community Integration Questionnaire (CIQ), Centre for Epidemiological Studies-Depression (CES-D), EuroQol and Employability Rating Scale (ERS). The study showed overall significant improvements (MANOVA T^2=4.311, $F_{10,12}$ 6.035, p=0.002) in the domains of patients' emotional well-being, quality of life, level of community integration, and employability directly after treatment. Independent living rose from 42% to 75%. Further improvements were seen at one year follow up.

The preliminary effectiveness of the BIP as described in chapter 3 was further substantiated by a study reported in **chapter 4**. This prospective cohort study used a three-months waiting list control period and a one-year follow up in a new and larger sample of 70 patients. Outcome measures were the CIQ, ERS, living situation, school, work situation, work hours, CES-D, EuroQOL quality of life scale (2 scales), World Health Organization Quality of Life Scale Abbreviated (WHO-QOL-BREF; 5 scales) and the Global Assessment of Functioning (GAF) scale. There was an overall significant time effect for all outcome measures (MANOVA T^2=26.16, $F_{36,557}$134.9, p=0.000). The effect sizes for the CIQ, ERS, work hours and GAF were

large (partial η^2 0.25, 0.35, 0.22 and 0.72, respectively). The effect sizes were moderate for 7 of the 8 emotional well-being and quality of life (sub)scales (partial η^2 0.11–0.20). The WHOQOL-BREF environment subscale showed a small effect size (partial η^2 0.05). Living independently rose from 25.4% before treatment to 72.4% after treatment. Thus, this study showed significant improvements in the domains of independent living, societal participation, emotional well-being and quality of life. The stability of the outcome measures at the two assessments before the intervention supported the notion that the included patients did no longer show spontaneous recovery. Hence, the observed effects were most likely attributable to the treatment itself. Nearly all beneficial effects were maintained at one-year follow up or even showed further improvements.

To study the effects of comprehensive rehabilitation programmes on the primary caregivers of patients with chronic acquired brain injury, responsive and validated outcomes are needed. However, with respect to the emotional burden in caregivers of patients with acquired brain injury, outcome measures are scarce and poorly validated. In **chapter 5**, a study was described concerning the psychometric properties of the Involvement Evaluation Questionnaire for Brain Injury (IEQ-BI), a scale measuring the emotional burden in caregivers. Ninety-eight caregivers filled in the IEQ-BI, of which 41 caregivers (of patients enrolled in the study reported in chapter 4) did this twice (before and after the persons they cared for had started the BIP), to determine its internal consistency, discriminant validity and responsiveness. The IEQ-BI had good internal consistency (Cronbach's α=0.73–0.84, Intraclass Correlation Coefficient=0.69–0.76) and moderate to good responsiveness (Cohen's d=0.36, Intraclass Correlation Coefficient=0.80). The discriminant validity with respect to the General Health Questionnaire (GHQ; psychological health) and the Family Assessment Device (FAD; family functioning) was also good. The results of this study provide a first indication for the IEQ-BI being a potentially sound tool for the assessment of emotional burden in caregivers of patients with chronic acquired brain injury.

Most outcome studies report on the effects of treatment on patients, but the concomitant effects on caregivers of patients are scarcely studied. In **chapter 6**, we reported on the effectiveness of the BIP with regard to the caregivers' emotional burden as assessed with the IEQ-BI. In addition, the GHQ and the FAD were used as outcome measures. With regard to emotional burden as well as psychological health, the results showed significant changes at follow up (partial η^2 0.05–0.17) compared to the moment of inclusion into the programme, whereas family functioning did not show significant time effects. Remarkably, the significant improvements occurred already at the start of treatment, with only slight (insignificant) further improvements during follow up. This pattern of results indicated a decrease

in emotional burden and better psychological health of the caregivers *in anticipation of* the patients' treatment. These improvements persisted until one year later. It was speculated that feelings of hope and reduction of distress were important underlying mechanisms. In this line of reasoning, the stability of the effects at follow up would reflect the fulfilment of expectations.

Residential community reintegration programmes are intensive and, thus, expensive. In **chapter 7**, we reported on the estimated costs of the BIP as well as the healthcare costs, informal care costs, and production costs related to the brain injury in the year before treatment and in the year following treatment. The BIP intervention costs added up to a total of 68,400 Euro per patient. Comparing the costs during the year before with the year after the BIP, the informal care by the caregivers significantly decreased ($p<0.05$) and the productivity losses by the patients decreased, although not significantly, while health care consumption somewhat increased ($p<0.05$). Yet, the average societal costs per patient related to the brain injury in the year preceding the BIP were 48,449 Euro, whereas in the year following the BIP these costs were estimated to be 39,773 Euro. This significant reduction of societal costs ($p<0.05$) implicated that a breakeven point is reached after 8 years. Because the mean age of the patients was relatively young (approximately 30 years), the profit of the BIP treatment probably stretches out over a long period (approximately 50 years). It was concluded that the reduction of societal costs after the BIP justifies the intensity and expenses of the programme.

Finally, in **chapter 8**, the findings of all studies have been discussed in the light of existing evidence for comprehensive rehabilitation programmes. The preliminary results of an ongoing study concerning the long-term follow up (three years) after BIP treatment have also been presented. These preliminary results indicated that the effects of BIP treatment in the domains of emotional well-being, quality of life, community integration, employability and living situation are maintained even after three years.

The research presented in this thesis was conducted from the perspective of patients, their caregivers as well from a socio-economic perspective and contributes to information about the (cost-) effectiveness of residential community reintegration programmes. Based on the results, it seems justified to conclude that this type of treatment should be available for all patients with chronic acquired brain injury that suffer from psychosocial problems hampering societal participation. Future research should make use of more rigorous study designs to further enhance the evidence level of residential community reintegration programmes.

10
Samenvatting

Het algemene doel van de onderzoeken die in dit proefschrift gepresenteerd worden, was het beschrijven en vergroten van het bewijs voor de effectiviteit van intensieve klinische neuropsychologische revalidatieprogramma's gericht op maatschappelijke reïntegratie voor patiënten met chronisch verworven hersenletsel en, meer specifiek, het bestuderen van de effectiviteit van een Nederlands klinisch revalidatieprogramma: het Brain Integration Programme (BIP). Het BIP biedt geïntegreerde cognitieve, emotionele, gedragsmatige, fysieke en arbeidsgerichte revalidatie aan patiënten in de chronische fase na verworven hersenletsel, die niet in staat zijn deel te nemen aan 'reguliere' ambulante programma's als gevolg van beperkingen in sociaal functioneren, emotionele controle, verrichten van arbeid en zelfstandig wonen. Vaak gaan deze beperkingen gepaard met gedragsproblemen. De essentie van het programma is dat patiënten leren een evenwicht te vinden in hun dagelijkse activiteiten met betrekking tot huishoudelijk functioneren, werk, vrije tijd en sociale interactie, rekening houdend met hun individuele capaciteiten en beperkingen. Om dit doel te bereiken is het realiseren van een optimaal aangepaste omgeving van het grootste belang.

In **hoofdstuk 1** werd een overzicht gegeven en het doel van dit proefschrift beschreven.

Om het niveau van bewijs voor de effectiviteit van intensieve neuropsychologische revalidatieprogramma's voor patiënten met chronisch verworven hersenletsel te bepalen werd een systematische review uitgevoerd die is beschreven in **hoofdstuk 2**. Deze review had drie doelen. Het eerste doel was het bepalen van de effectiviteit van de drie vormen van intensieve revalidatieprogramma's die in de literatuur onderscheiden worden (te weten neuropsychiatrische programma's, klinische intensieve neuropsychologische revalidatieprogramma's gericht op maatschappelijke reïntegratie en intensieve (holistische) dagbehandelingprogramma's). Het tweede doel was te beoordelen of patiëntkarakteristieken verschilden tussen de specifieke programma's. Het derde doel was de essentiële verschillen in de interventies tussen deze programma's vast te stellen. Dertien artikelen werden gevonden die aan de vooraf vastgestelde (minimale) kwaliteitscriteria voldeden. Negen artikelen beschreven intensieve dagbehandelingprogramma's, waaronder twee RCT's, vier gecontroleerde vergelijkingsstudies en drie ongecontroleerde longitudinale studies. Drie studies onderzochten klinische intensieve neuropsychologische revalidatieprogramma's, waaronder één gecontroleerde vergelijkingsstudie en twee ongecontroleerde longitudinale studies. Met betrekking tot de neuropsychiatrische programma's werd slechts één ongecontroleerde longitudinale studie gevonden. Door het beperkte aantal studies en hun lage methodologische kwaliteit kon de effectiviteit van de intensieve revalidatieprogramma's niet bepaald worden. Des-

ondanks werd voorlopig geconcludeerd dat het dagelijks functioneren van patiënten en hun integratie in de maatschappij verbeterd kan worden door intensieve revalidatieprogramma's, met het hoogste bewijsniveau voor de effectiviteit van intensieve dagbehandelingprogramma's. De demografische en letsel-gerelateerde data werden onvoldoende beschreven in de artikelen om de indicatie voor en de effectiviteit van de behandelprogramma's te kunnen differentiëren op basis van patiëntkarakteristieken. Wat de interventiekarakteristieken betreft, verschilden de revalidatieprogramma's aanzienlijk qua behandelduur. De neuropsychiatrische programma's duurden meer dan een jaar, de klinische intensieve neuropsychologische revalidatieprogramma's tussen 6 maanden en een jaar, terwijl de intensieve dagbehandelingprogramma's tussen 6 weken en 6 maanden in beslag namen. Door de beperkte beschrijving van de inhoud en intensiteit van de revalidatieprogramma's konden geen andere systematische verschillen gevonden worden en was het niet mogelijk om de effectiviteit van behandelprogramma's te relateren aan een specifiek patiëntprofiel. Aanbevolen werd dat in toekomstige effectstudies gericht op intensieve revalidatieprogramma's voor patiënten met chronisch verworven hersenletsel een vorm van controle zou moeten worden toegepast, binnen danwel tussen proefpersonen, en dat zowel de relevante patiëntkarakteristieken (bijvoorbeeld demografische en klinische kenmerken en niveau van functioneren) als de gedetailleerde interventiekarakteristieken helder beschreven behoren te worden.

In **hoofdstuk 3** werd het BIP gedetailleerd beschreven inclusief de behandelintensiteit, behandelduur en betrokken disciplines. Het BIP werkt met een gestandaardiseerd behandelprotocol dat drie modules omvat:

1. zelfstandig wonen;
2. sociaal-emotioneel functioneren; en
3. werk.

De gemiddelde behandeltijd werd geschat op 100 uur per persoon voor de module 'zelfstandig wonen', 110 uur per persoon voor de module 'sociaal-emotioneel functioneren' en 44 uur per persoon voor de module 'werk'. De aanvullende begeleiding en training door de verpleegkundigen werd ruwweg geschat op 1,5 uur per persoon per dag. De gemiddelde duur van het BIP was 196 dagen. We beschreven de resultaten van een prospectieve cohortstudie met 24 patiënten. Uitkomstmaten waren de Community Integration Questionnaire (CIQ), de Centre for Epidemiological Studies-Depression (CES-D), EuroQol en de Employability Rating Scale (ERS). De studie toonde over alle uitkomstmaten tezamen significante verbeteringen aan (MANOVA T^2=4.311, $F_{10,12}$ 6.035, p=0.002) op de domeinen emotioneel welbevinden, kwaliteit van leven, niveau van integratie in de maatschappij en werkinzetbaarheid direct na de behandeling. Zelfstandig wonen nam toe van 42% naar 75%. Verdere verbeteringen werden gevonden bij de follow-up na een jaar.

De preliminaire effectiviteit van het BIP, zoals beschreven in hoofdstuk 3, werd verder onderbouwd met het onderzoek zoals beschreven in **hoofdstuk 4**. Deze prospectieve cohortstudie gebruikte een wachtlijst-controleperiode van 3 maanden en een follow-up van één jaar bij een nieuwe en grotere onderzoeksgroep van 70 patiënten. Uitkomstmaten waren de CIQ, ERS, woonsituatie, werksituatie, werkuren, CES-D, EuroQol (2 schalen), Wereldgezondheidsorganisatie Quality of Life Scale Abbreviated (WHOQOL-BREF; 5 schalen) en de Global Assessment of Functioning (GAF-)schaal. Er was over alle uitkomstmaten tezamen een significant tijdseffect (MANOVA T^2=26.16, $F_{36,557}$134.9, p=0.000). De effectgrootten van de CIQ, ERS, werkuren en GAF waren groot (partiële η^2 was 0.25, 0.35, 0.22 en 0.72, resp.). De effectgrootten van 7 van de 8 (sub)schalen voor emotioneel welbevinden en kwaliteit van leven waren matig (partiële η^2 0.11–0.20). De WHOQOL-BREF-subschaalomgeving had een kleine effectgrootte (partiële η^2 0.05). Zelfstandig wonen steeg van 25.4% vóór de behandeling naar 72.4% na de behandeling. Hiermee toonde dit onderzoek significante verbeteringen aan op de domeinen zelfstandig wonen, participatie in de maatschappij, emotioneel welbevinden en kwaliteit van leven. De stabiliteit van de uitkomstmaten op de twee metingen voor de behandeling ondersteunde het idee dat de geïncludeerde patiënten geen spontaan herstel vertoonden. Daarom werd geconcludeerd dat de gevonden effecten het meest waarschijnlijk aan de behandeling zelf toegeschreven kunnen worden. Bijna alle gunstige effecten bleken na een jaar nog behouden of vertoonden zelfs verdere verbetering.

Om het effect van intensieve revalidatieprogramma's op de primaire mantelzorgers van patiënten met chronisch verworven hersenletsel te kunnen onderzoeken zijn responsieve en gevalideerde instrumenten nodig. Echter, met betrekking tot de emotionele belasting voor dergelijke mantelzorgers zijn deze instrumenten schaars en slecht gevalideerd. In **hoofdstuk 5** werd een studie beschreven die betrekking had op de psychometrische eigenschappen van de Betrokkenen Evaluatie Schaal - Hersenletselversie (Involvement Evaluation Questionnaire for Brain Injury (IEQ-BI)) die de emotionele belasting van mantelzorgers meet. Achtennegentig mantelzorgers vulden de IEQ-BI in, waarvan 41 mantelzorgers (van patiënten geïncludeerd in het onderzoek gerapporteerd in hoofdstuk 4) dit tweemaal deden (voor- en nadat de patiënten voor wie ze zorgden, startten met het BIP) om de interne consistentie, discriminantevaliditeit en responsiviteit te bepalen. De IEQ-BI had een goede interne consistentie (Cronbach's α=0.73–0.84, Intraclass Correlation Coefficient=0.69–0.76) en matige tot goede responsiviteit (Cohen's d=0.36, Intraclass Correlation Coefficient=0.80). De discriminante validiteit ten opzichte van de General Health Questionnaire (GHQ; psychische gezondheid) en de Family Assessment Device (FAD; familiefunctioneren) was ook goed. De resultaten van dit onderzoek gaven een eerste indicatie dat de IEQ-BI een potentieel

geschikt instrument is om de emotionele belasting te meten bij mantelzorgers van patiënten met chronisch verworven hersenletsel.

De meeste effectstudies rapporteren over het effect van behandeling op patiënten, maar het bijkomende effect op mantelzorgers wordt nauwelijks onderzocht. In **hoofdstuk 6** werd een onderzoek beschreven naar de effectiviteit van het BIP met betrekking tot de emotionele belasting bij mantelzorgers gemeten met de IEQ-BI. Daarnaast werden de GHQ en de FAD gebruikt als uitkomstmaten. Zowel met betrekking tot emotionele belasting als psychische gezondheid toonde de studie significante veranderingen aan bij de follow-up (partiele η^2 0.05–0.17) vergeleken met het moment van inclusie in het programma, maar op het gebied van familiefunctioneren werd geen significant tijdseffect gevonden. Opmerkelijk was dat de significante verbeteringen al bij de start van de behandeling optraden met slechts lichte, niet significante, verdere verbeteringen nadien. Dit patroon duidt op een vermindering van de emotionele belasting en verbetering van de psychische gezondheid van de mantelzorger *in anticipatie op* de behandeling van de patiënt. Deze verbeteringen waren ook een jaar na de behandeling nog aanwezig. Speculatief werd gesteld dat de gevoelens van hoop en vermindering van stress belangrijke onderliggende mechanismen waren en dat de stabiliteit van het effect bij de follow-up aangeeft dat de verwachtingen uitgekomen zijn.

Intensieve klinische neuropsychologische revalidatieprogramma's zijn tijdrovend en daardoor zijn de kosten hoog. In **hoofdstuk 7** rapporteerden we over de geraamde kosten van het BIP evenals over de gezondheidszorgkosten, mantelzorgkosten en productiviteitsverliezen gerelateerd aan het hersenletsel in het jaar vóór en het jaar na de behandeling. De BIP-behandelkosten bedroegen opgeteld een totaal van 68.400 Euro per patiënt. Bij vergelijking van de kosten gedurende het jaar voorafgaand aan met het jaar volgend op de BIP, bleek dat het productiviteitsverlies bij mantelzorgers (significant) en patiënten (niet significant) afnam, terwijl de gezondheidszorgkosten toenamen ($p<0.05$). Tezamen waren de gemiddelde maatschappelijke kosten in het jaar voorafgaand aan de BIP 48.449 Euro, terwijl deze in het jaar volgend op de BIP geschat werden op 39.773 Euro. Deze significante vermindering van de maatschappelijke kosten ($p<0.05$) gaven aan dat het 'break-even point' na 8 jaar bereikt wordt. Aangezien de gemiddelde leeftijd relatief laag was (bijna 30 jaar), strekt de winst van de het BIP zich uit over een lange periode (ongeveer 50 jaar). Derhalve werd geconcludeerd dat de afname van de maatschappelijke kosten na het BIP de intensiteit en de kosten van de behandeling rechtvaardigt.

Tenslotte werden in **hoofdstuk 8** de resultaten van alle studies in dit proefschrift besproken in het licht van het bestaande bewijs voor intensieve revalidatieprogramma's. Tevens werden de voorlopige resultaten van een lopend onderzoek met

betrekking tot de langetermijn follow-up (drie jaar) na het BIP gepresenteerd. Deze eerste tussentijdse resultaten gaven aan dat de effecten van het BIP op de domeinen emotioneel welbevinden, kwaliteit van leven, integratie in de maatschappij, werkinzetbaarheid en woonsituatie zelfs na drie jaar behouden blijven.

Het onderzoek zoals gepresenteerd in dit proefschrift werd uitgevoerd vanuit het perspectief van de patiënten en hun mantelzorgers, evenals vanuit een sociaal-economisch perspectief, en draagt bij aan kennis over de (kosten)effectiviteit van intensieve klinische neuropsychologische revalidatieprogramma's. Gebaseerd op de resultaten lijkt het gerechtvaardigd te concluderen dat dit type behandeling beschikbaar zou moeten zijn voor alle patiënten met chronisch verworven hersenletsel die psychosociale problemen ondervinden welke de maatschappelijke participatie belemmeren. Toekomstig onderzoek zou gebruik moeten maken van sterkere onderzoeksdesigns om het niveau van bewijs van de effectiviteit van klinische neuropsychologische revalidatieprogramma's verder te verhogen.

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Dankwoord

De 'Slippery Slope of Science' ga je gelukkig niet alleen op.

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verwaarloosde. Jij bewonderde mijn geduld en doorzettingsvermogen, ik bewonder jouw scherpe analyses en je sociale en invoelende instelling. Samen hebben we ook dit project afgerond. Dit was ook weer zo'n groots project, waarvan we er nu al vele hebben gedaan in onze ruim 16 jaar. Ik heb al zin in onze volgende en ben dolblij dat we die aan elkaars zijde samen aan kunnen gaan.

Curriculum Vitæ

Gert Geurtsen werd geboren op 25 november 1963 in Ederveen als zoon van Gerrit Geurtsen en Jannig Geurtsen-Lodder. In 1981 behaalde hij zijn havo-diploma en in 1983 volgde het vwo-diploma, beide aan het Christelijk Lyceum te Veenendaal. Aansluitend begon hij met de studie psychologie aan de RijksUniversiteit te Groningen. In 1989 studeerde hij af met als afstudeerrichting Klinische Psychologie.

Tijdens zijn eerste banen bij Psychiatrisch Ziekenhuis Veldwijk en InteraktContour ontwikkelde hij zich tot neuropsycholoog. Sinds 1999 is hij BIG-geregistreerd als Gezondheidszorgpsycholoog.

Vanaf 2000 werkt hij bij revalidatiecentrum Groot Klimmendaal als behandelaar en sinds 2003 ook als onderzoeker.

In 2009 is hij BIG-geregistreerd als Klinisch Neuropsycholoog

Sinds 1994 is Gert Geurtsen samen met Jeroen Tazelaar en in 2002 zijn zij getrouwd.